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**The design and evaluation of a self-management  
intervention for patients admitted to hospital with  
heart failure.**

Submitted by Kathleen Mulligan

for the degree of PhD at University College London

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## **ABSTRACT**

This thesis describes the development and evaluation of a self-management intervention for people admitted to hospital with heart failure due to left ventricular systolic dysfunction. The intervention was delivered by a heart failure nurse specialist, following optimisation of in-patient medical treatment. It consisted of two sessions during the hospital stay, a home visit and follow-up telephone call. The content of the intervention and techniques for its delivery were detailed in a manual.

The intervention was evaluated in a single-blind randomised controlled trial. The primary outcomes were the number of readmissions to hospital and duration of hospital stay in the 90 days after discharge from the index admission. Other outcomes included readmissions to hospital and duration of hospital stay in the 12 months after discharge, mortality, quality of life and psychological well-being. Process variables included self-management behaviours and cognitions. One hundred and sixty-five patients were recruited to the study and they were followed up for a period of 12 months.

The intervention had a significant effect on aspects of self-management behaviour but did not demonstrate a significant effect on readmission to hospital or mortality in the total sample. However, a post-hoc sub-group analysis identified a significant impact of the intervention in those patients who were newly diagnosed with heart failure. Newly diagnosed patients in the intervention group had fewer admissions to hospital for heart failure and spent fewer days in hospital for heart failure during the 12 month follow-up period than those in the control group. The implications of the findings for future research and intervention development are discussed.

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## **THE STUDY TEAM**

This study was a collaboration between the Department of Academic & Cardiovascular Medicine, Whittington Hospital, the Centre for Behavioural and Social Sciences in Medicine, UCL and the National Heart & Lung Institute, Imperial College London.

The core steering committee for this project comprised Dr. Suzanna Hardman, Professor Stanton Newman, Professor Martin Cowie and Professor David Patterson. Other members of the study team were Dr. Rosaire Gray, Dr. Alex Zaphiriou, Ms. Patsy Hargrave and myself.

Dr. Suzanna Hardman, consultant cardiologist, is the principal investigator on the study. She initiated the study, arranged the collaborations and obtained study funding along with co-applicants, Professors Stanton Newman, Martin Cowie and David Patterson. Dr. Hardman managed the study, including study development and design, implementation of study procedures and clinical care. Dr Hardman is also a co-supervisor on the work involved in this thesis.

Professor Stanton Newman, professor of health psychology, was a co-applicant for grant funding, advised throughout the study on design and analysis and managed the development of the self-management intervention and training of the heart failure nurse specialist. He is the principal supervisor of the work involved in the development, data analysis and writing of this thesis.

Professor Martin Cowie, consultant cardiologist, was a co-applicant for grant funding and advised throughout the study on design and data analysis.

Professor David Patterson, consultant cardiologist, was a co-applicant for grant funding and advised on study design. He also reviewed all hospital readmissions of study patients to classify the reason for readmission.

Dr. Rosaire Gray, consultant cardiologist, reviewed all hospital readmissions of study patients to classify the reason for readmission.

Dr. Alex Zaphiriou, clinical research fellow in cardiology, identified potential study participants, recruited patients to the study, provided clinical care and collected the clinical data for the study. He also collected data on hospital readmissions and mortality, along with myself. Dr Zaphiriou also was responsible for health economic analysis of the study data.

Ms. Patsy Hargrave, heart failure nurse specialist, contributed to the development of the self-management intervention and also delivered the intervention.

I contributed to the design of the study, the development of the self-management intervention and training of the heart failure nurse specialist. I identified potential study participants, collected the questionnaire data and shared the collection of hospitalisation and mortality data with Dr. Zaphiriou. I also maintained the study database and conducted the statistical analysis reported in this thesis.

# **CHAPTER 1**

## **INTRODUCTION**

Heart failure is a common and increasing health problem and, despite advances in available medical therapies, prognosis remains poor, both in terms of high mortality rates and frequent hospital admissions. There has been an increasing recognition of shortcomings in treatment delivery that contribute to poor prognosis and in order to rectify these weaknesses, delivery of medical management of heart failure has undergone considerable change in recent years.

A significant aspect of this change in many countries has been the introduction of disease management programmes. Although different models exist, most programmes involve intensive case management with frequent patient follow-up, usually by a heart failure nurse specialist. Not only does this approach place a significant demand on health care resources but it also neglects the role of patients in managing their illness. The current study aimed to address this issue by developing an intervention that would enhance patients' self-management of their heart failure. The chapters that follow describe the background to the study, the development of the self-management intervention and its evaluation in a randomised controlled trial.

Chapter two provides a description of heart failure and the demands that it places on the patient and the healthcare system. The chapter also provides an overview of medical management of heart failure and approaches that have been taken to try to bring about improvements. Shortcomings in patients' self-management of their heart failure are also described and these raise the need for an intervention to enhance self-management.

Chapter three describes how a self-management approach is relevant in heart failure. This chapter outlines the theoretical bases of self-management, strategies that can be used to enhance self-management and factors that have been found to influence self-management in heart failure. A systematic review of interventions that included a component addressing self-management of heart failure was conducted and the results are presented. This review was performed to inform the development of the self-management intervention in this thesis.

The development of the intervention is described in chapter four and a full description of the intervention is set out in the manual in Appendix A.

The randomised controlled trial that was conducted to evaluate the intervention is covered in chapters five to ten. These chapters describe the design of the study, the participants recruited and the impact of the intervention on primary and secondary outcomes. It was recognised that a single type of intervention is unlikely to be suitable for all patients and therefore an important part of this study was to examine whether particular factors predicted benefit from the intervention and this analysis is included.

The final chapter discusses the findings of the study, its strengths and limitations and directions for future research.

## **CHAPTER 2**

### **HEART FAILURE**

This chapter provides a description of heart failure, its aetiology and epidemiology. A summary of the health outcomes of heart failure is provided, including mortality, admission to hospital and the impact of heart failure on quality of life and psychological well-being. This chapter also includes details of recommended treatment for heart failure and a summary of recognised shortcomings in heart failure management. The chapter concludes with a brief overview of disease management programmes that have been introduced to try to overcome these shortcomings. The need for approaches to heart failure management which do not rely on intensive case management but help to enhance patient self-management is addressed.

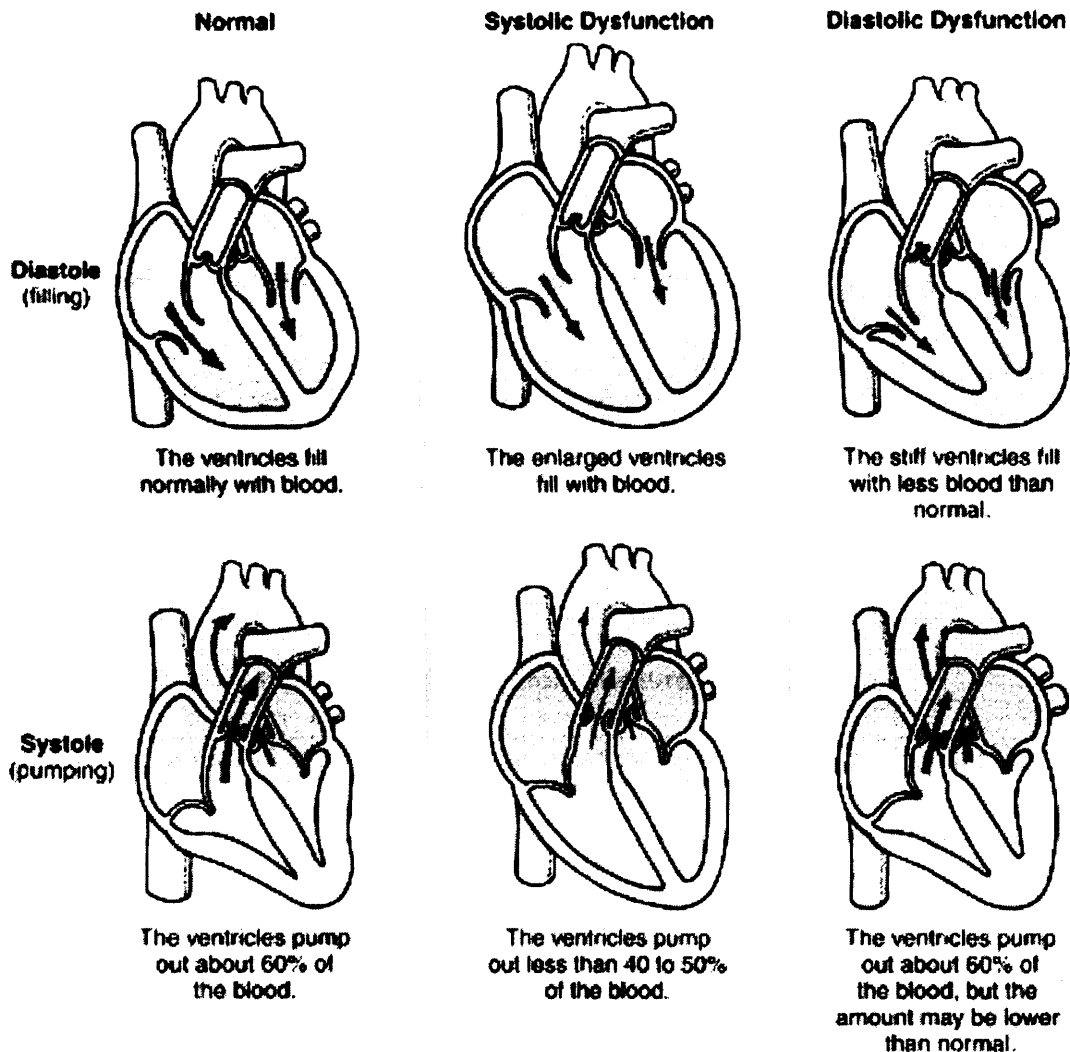
This chapter aims to provide an overview of current management of heart failure while chapters 3 and 4 aim to show how heart failure management at the time the study began informed its development.

#### **2.1 Definition and clinical features (Figure 2.1)**

Heart failure is a clinical syndrome that can result from any condition that damages the ability of the heart to pump blood around the body to meet its requirements. The pumping action of the heart is impaired, either in systole, so that the heart can not pump hard enough, or in diastole, so that the heart is unable to relax sufficiently to allow its chambers to fill with blood. In both cases, blood flow is reduced and an insufficient quantity is pumped. This leads to a rise in pressure in the heart's chambers, causing blood returning to the heart to build up in the lungs or veins. Heart failure may be predominantly left-sided or right-sided. In left-sided heart failure, the left side of the

heart is impaired in its ability to pump blood into the body and so it backs-up behind the left ventricle, causing fluid retention in the lungs. In right-sided heart failure, the right side of the heart is impaired in its ability to pump venous blood into the pulmonary circulation, causing blood to back up in the body.

**Figure 2.1 Pumping and filling problems in heart failure (Kranias, 2006)**



The body's attempt to compensate for reduced blood flow causes the kidneys to retain water and sodium in the body. Excess fluid may leak from blood vessels into body tissues leading to swelling (oedema) which usually occurs in the feet, ankles and legs. In severe cases, fluid may accumulate in the abdomen (ascites). Fluid build up in the lungs (pulmonary oedema) leads to symptoms of breathlessness (dyspnoea) which can be particularly problematic when lying down (orthopnoea) and can also lead to waking



at night (paroxysmal nocturnal dyspnoea). Impaired circulation may lead to fatigue and reduced cognitive abilities (Soufer, 1992). Heart failure can also present with a wide range of difficult to diagnose and non-specific symptoms. The guidelines of the European Society of Cardiology (ESC), (Remme & Swedberg, 2002; Task Force for the Diagnosis and Treatment of Chronic Heart Failure et al., 2005), specify that a diagnosis of heart failure requires fulfilment of the following criteria:

1. Symptoms of heart failure (at rest or in exercise)
2. Objective evidence of cardiac dysfunction (at rest)  
and (in cases where the diagnosis is in doubt)
3. Response to treatment directed towards heart failure.

The New York Heart Association (NYHA) classification (Dolgin, 1994) is widely used to classify severity of heart failure according to how limited patients are due to symptoms during physical activity. The classifications are shown in Table 2.1

**Table 2.1 New York Heart Association Heart Failure Classification**

<b>Class I</b> No limitation: ordinary physical exercise does not cause undue fatigue, dyspnoea, or palpitations (by definition treated heart failure)
<b>Class II</b> Slight limitation of physical activity: comfortable at rest but ordinary activity results in fatigue, palpitations, or dyspnoea
<b>Class III</b> Marked limitation of physical activity: comfortable at rest but less than ordinary activity results in symptoms
<b>Class IV</b> Unable to carry out any physical activity without discomfort: symptoms of heart failure are present even at rest with increased discomfort with any physical activity

## 2.2 Aetiology

The most common causes of heart failure in developed countries are myocardial infarction, hypertension, or a combination of both. Other common causes include valve disease, alcohol abuse and idiopathic dilated cardiomyopathy, of which some of the

latter may have a genetic basis. The contribution of diabetes, atrial fibrillation and coronary artery disease in the absence of myocardial infarction appear to be important but require further clarification (McMurray & Pfeffer, 2005). Heart failure is a syndrome, not a disease, therefore it is important to identify the underlying aetiology in order to guide treatment. Some causes may be reversible, for example, heart failure due to valve disease may be reversed by valve replacement surgery.

## **2.3 Epidemiology**

Between 1-2% of the adult population in developed countries has heart failure. It is estimated that almost 900,000 people in the UK have heart failure, of whom approximately 54% are male. Prevalence increases with age, from about 1 in 35 in those aged 65-74, rising to 1 in 15 in those aged 75 to 84 and 1 in 7 in those aged 85 and over (Petersen, Rayner, & Wolstenholme, 2002). The epidemiology of heart failure among different ethnic groups is not well documented as most epidemiological studies have recruited almost exclusively white patients or have not reported ethnicity (Sosin, Bhatia, Davis, & Lip, 2004). There is nevertheless some evidence that the risk of heart failure may be higher among Afro-Caribbeans and South Asians than among the white population in the UK. Chaturvedi (Chaturvedi, 2003) reported a relative risk of heart failure in those aged 60-79 of 3.1 for Afro-Caribbeans and 5.2 for South Asians.

Aetiology of heart failure has also been found to differ between ethnic groups. Lip et al (Lip, Zarifis, & Beevers, 1997) found that among white patients the most common aetiological factors were coronary heart disease and hypertension, among Indo-Asian patients they were coronary artery disease and diabetes and among black Afro-Caribbean patients they were hypertension and diabetes. Some of these differences may be explained by the difference in prevalence of these aetiological factors between the ethnic groups.

It is predicted that the prevalence of heart failure will increase significantly, for example, Bonneux, Barendregt, Meeter, Bonsel, & van der Maas (1994) predicted that in the Netherlands, heart failure arising from coronary heart disease would rise by approximately 70% between 1985 and 2010. In Australia, prevalence of heart failure was projected to increase by approximately 50% between 1996 and 2016 (Kelly, 1997). Recent population data are not available to assess whether these predictions are on course to be realised however a number of factors would support an increasing prevalence. Trends in heart failure between 1950 and 1999 found that incidence has remained fairly stable since 1970 whereas survival rates have improved (Levy, Kenchaiah, Larson et al., 2002), a phenomenon which would result in an increased prevalence. The proportion of the elderly in the population is increasing which is likely to see an associated rise in prevalence of hypertension and coronary heart disease, two of the main risk factors for heart failure (McMurray & Stewart, 2000). Increasing rates of obesity and diabetes could also lead to increases in heart failure (Kenchiah, Evans, Levy et al, 2002; Kamalesh & Nair, 2005) and increasing use of treatments which extend life will also have the effect of increasing its prevalence (Redfield, 2002).

## **2.4 Health Outcomes**

In spite of advances in treatment, the prognosis of heart failure remains poor with high mortality and morbidity.

### **2.4.1 Mortality**

Population studies have found mortality rates of 30-40% within 1 year of diagnosis and 60-70% within 5 years. Rates are higher in those admitted to hospital for heart failure (McMurray & Pfeffer, 2005). The mortality rate for heart failure is worse than that for many forms of cancer - one study found that when heart failure was compared with

cancers of the breast, lung, large bowel and ovary, only lung cancer had a higher mortality rate (Stewart, MacIntyre, Hole, Capewell, & McMurray, 2001). There is however some evidence that prognosis may be improving. A study of heart failure admissions to hospitals in Scotland found that between 1986 and 1995 the 30-day mortality rate fell by 26% in men and 17% in women (MacIntyre, Capewell, Stewart et al., 2000). McMurray & Stewart (2002) put forward the hypothesis that this may have been attributable to new medical treatments. Schaufelberger, Swedberg, Koster, Rosen, & Rosengren (2004) also found improvements between 1988 and 2000 in 30-day and 1-year mortality among patients in Sweden hospitalised for the first time for heart failure. They reported that these improvements coincided with the established use of ACE-inhibitor therapy, the introduction of beta-blockers and home-care programmes for heart failure, and more effective treatment and prevention of underlying diseases but commented that the full benefits of beta-blocker and spironolactone treatments would probably not have been achieved during the study period. In England, Mehta, Dubrey, McIntyre et al (2006) also reported lower mortality rates than were found in a similar study performed approximately a decade earlier (Cowie, Wood, Coats et al., 2000).

These changes can make it difficult to compare mortality in intervention studies that have been performed in different time periods.

## **2.4.2 Morbidity**

### **2.4.2.1 Hospital admissions**

The high morbidity in heart failure is seen in the large number of hospital admissions. Heart failure accounts for approximately 1-2% of healthcare spending (Berry, Murdoch, & McMurray, 2001), of which in-patient hospital treatment comprises almost two-thirds of the costs (McMurray, Hart, & Rhodes, 1993). Approximately 5% of all medical

admissions to hospital are for heart failure and it is the single most common reason for admission in those aged over 65. Hospital admissions place a significant burden on patients and their families as well as on the health service. The British Heart Foundation estimated from routine hospital statistics that in 2000/2001 there were approximately 86,000 hospital admissions for heart failure to National Health Service (NHS) hospitals in the UK, with an estimated cost of £379 million (Petersen et al., 2002). Hospital admissions for heart failure in England have been projected to increase by approximately 50% between 2000 and 2026, mostly due to the aging of the population (Gnani & Ellis, 2001).

The risk of repeated hospital admissions is also high. The EuroHeart Failure survey programme (Cleland, Swedburg, Foliath et al., 2003) found that of patients who survived the index admission, 24% were readmitted within 12 weeks of discharge.

#### **2.4.2.2 Quality of Life**

Heart failure has been found to impair quality of life more than many other chronic illnesses (Stewart et al, 1989). Stewart et al examined quality of life of 9385 adult out-patients using the SF-36, a measure of generic health-related quality of life (Ware & Sherbourne, 1992). Fifty-four percent of respondents had at least one of nine chronic conditions. These were hypertension, diabetes, myocardial infarction, arthritis, chronic lung problems, gastrointestinal disorders, back problems, angina and heart failure. Patients with heart failure reported worse physical quality of life than all other conditions with the exception of those who had had a myocardial infarction. The mental quality of life of patients with heart failure was poorer than all except those with chronic lung problems and gastrointestinal disorders.

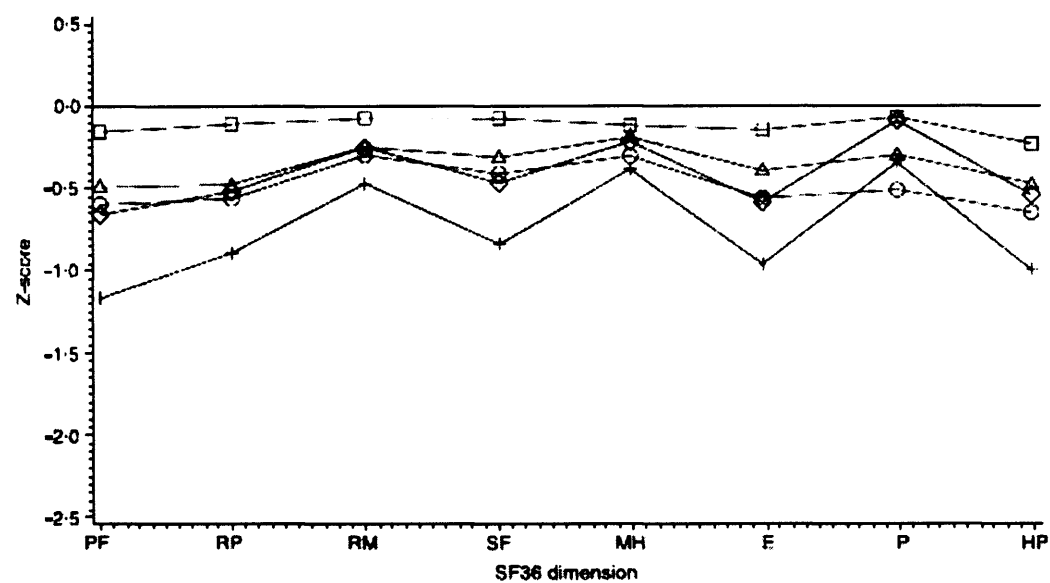
Hobbs et al (2002) also used the SF-36 measure of generic health-related quality of life in a population study in the West Midlands region of England. Patients were randomly

sampled from the general population and from 3 diagnostic categories on general practice registers. These categories were a diagnosis of heart failure, prescribed diuretic medication and patients considered at high risk of heart failure because of previous myocardial infarction, angina, hypertension or diabetes. The SF-36 was completed by 5961 people of whom 426 had a diagnosis of heart failure. When compared with the 3850 people sampled from the general population, patients with heart failure had significantly impaired quality of life on all 8 dimensions of the SF-36 – physical functioning, role limitations due to physical problems, role limitations due to emotional problems, social functioning, mental health, energy, pain and overall perception of health. When compared with patients with other common cardiac conditions (angina, previous myocardial infarction, atrial fibrillation or hypertension), patients with heart failure had poorer quality of life on all dimensions except pain, which was greater in those with angina (Figure 2.2).

When compared to patients with arthritis, chronic lung disease or depression, patients with heart failure were more severely impaired in physical functioning, role limitation due to physical problems and lack of energy than those with arthritis and chronic lung disease. They reported less pain than those with arthritis and better mental health and less role limitations due to emotional problems than those with depression. The extent of impairment in quality of life appeared to be related to NYHA classification with those in higher NYHA reporting poorer quality of life (Figure 2.3).

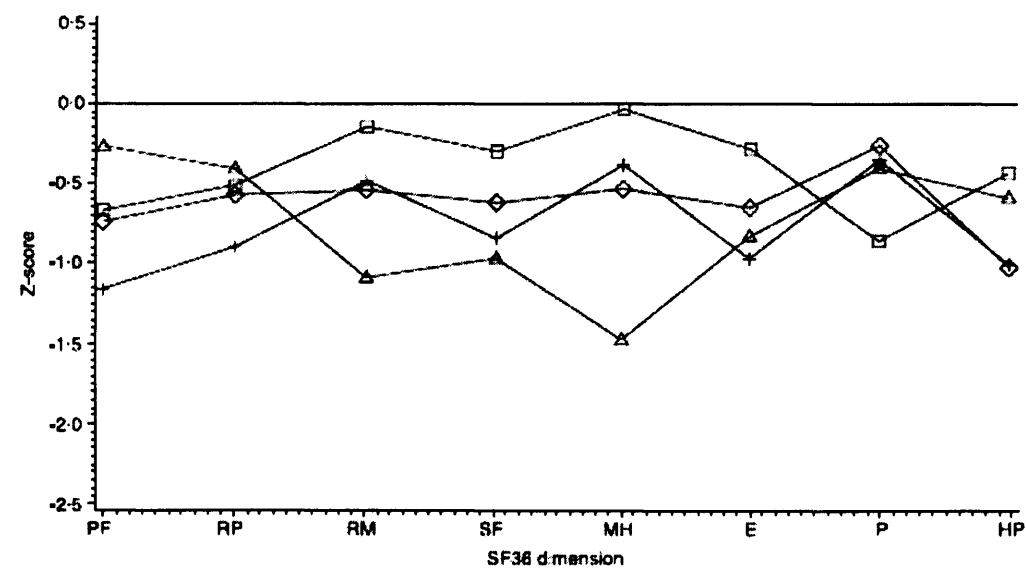


**Figure 2.2 Quality of life in patients with chronic cardiac diseases, including heart failure, compared to the general population. (Hobbs et al, 2002)**



**Figure 5** Z-scores of patients with various chronic cardiac diseases compared to the general population. PF=physical functioning; RP=role physical; RM=role mental; SF=social functioning; MH=mental health; E=energy; P=pain; HP=overall perception of health. —=general population; ◇=atrial fibrillation; □=angina; ○=high blood pressure; △=history of MI; +=diagnosed heart failure.

**Figure 2.3 Quality of life in patients with chronic medical conditions, including heart failure, compared to the general population (Hobbs et al, 2002)**



**Figure 6** Z-scores of patients with various chronic medical conditions, including heart failure, compared to the general population. PF=physical functioning; RP=role physical; RM=role mental; SF=social functioning; MH=mental health; E=energy; P=pain; HP=overall perception of health. —=general population; ◇=chronic bronchitis; +=diagnosed heart failure; □=arthritis; △=depression.

Quality of life is not only an important outcome in its own right but is also related to both morbidity and mortality. In the Studies of Left Ventricular Dysfunction (SOLVD) trial, the quality of life dimensions of heart failure symptoms, impairment in activities of daily living and patients' assessment of their general health were found to be independent predictors of heart failure related hospitalizations and mortality (Konstam, Salem, Pouleur et al., 1996).

#### **2.4.2.3 Psychological wellbeing**

Depression is common in heart failure although reported prevalence varies. This is probably due to differences in the assessment and criteria for classification of depression and in the study populations. Most studies use questionnaire assessments which identify 'possible' or 'probable' depression but a diagnostic interview is required to confirm the presence of clinical depression. The percentage identified as depressed using clinical interview is therefore likely to be smaller than when using questionnaire assessment. Reported prevalence of depression in out-patient populations of heart failure has ranged from 11% who met the criteria for syndromal depression by diagnostic interview schedule (Turvey, Schultz, Arndt, Wallace, & Herzog, 2002), to 48% who scored in the depressed range on the Beck Depression Inventory (Gottlieb, Khatta, Friedmann et al., 2004). A recent UK study used the Structured Clinical Interview for Diagnostic and Statistical Manual of mental disorders in a sample of 100 patients attending a community heart failure chronic disease management programme (Haworth, Moniz-Cook, Clark et al, 2005). They found that 29% were diagnosed with a depressive disorder.

Prevalence of depression may be higher among in-patient populations. Using a questionnaire assessment, Vaccarino, Kasl, Abramson, & Krumholz (2001) found that 77.5% scored within the depressed range. In a study that used clinical interview, 20%

met the criteria for a current major depressive episode and 16% met criteria for a current minor depressive episode (Freedland, Rich, Scala et al, 2003).

Depression appears in some studies to be more common in younger people and in women with heart failure (Freedland et al., 2003), although this finding is not consistent. There is also evidence for a relationship between depression and NYHA class, with higher rates of depression among those with greater functional limitation (Gottlieb et al., 2004). This study used a cross-sectional design therefore the causal direction is not established so while it is possible that greater functional limitation increases the risk of depression, it may also be the case that patients with more depressed mood perceive themselves to be more limited.

Depression appears to be associated with a poorer prognosis. Hospital readmission has been found to be more frequent in depressed patients and depression has also been found to predict mortality (Friedmann, Thomas, Liu et al, 2006; Faris, Purcell, Henein, & Coats, 2002). Vaccarino et al (2001) found that after adjustment for demographic factors, medical history, baseline functional status and clinical severity, an increasing number of depressive symptoms was associated with a significantly higher risk of the combined endpoint of functional decline or death. Depression appears to predict mortality independently of NYHA and left ventricular ejection fraction (LVEF) (Junger, Schellberg, Muller-Tasch et al., 2005). Poorer prognosis may be partly explained by poorer medication adherence by people who are depressed (DiMatteo, Lepper, & Croghan, 2000).

In contrast to depression, there is little research on anxiety in heart failure. A link between anxiety and depression in heart failure has been reported however (Freedland & Carney, 2000), in that anxious reactions to dyspnoea were found to be more common in depressed than non-depressed patients. Haworth et al, 2005 diagnosed an

anxiety disorder in 18% of heart failure patients attending a community disease management programme, which is higher than that found in healthy older adults (Lindesay, Briggs, & Murphy, 1989). Although anxiety is an important outcome in its own right, it has not been found to be related to prognosis. In the SOLVD clinical trial of the ACE-inhibitor enalapril, no association was found between anxiety and mortality or hospitalisation (Konstam et al, 1996), nor did Junger et al (2005) or Friedmann et al (2006) find anxiety to predict mortality.

## **2.5 Management of Heart Failure**

The evidence for medical management of heart failure relates mostly to heart failure due to left ventricular systolic dysfunction, which is the most common cardiac abnormality in heart failure (National Institute for Clinical Excellence, 2003). There is considerable debate about the diagnosis of heart failure due to diastolic dysfunction (National Institute for Clinical Excellence, 2003) and there is also a lack of consensus about its treatment (Vasan & Benjamin, 2001). Accordingly, the study described in this thesis was developed for patients with heart failure due to left ventricular systolic dysfunction and it is to this type of heart failure that the remainder of the thesis refers.

Guidelines for the management of heart failure have been produced by the American Heart Association (Hunt, Abraham, Chin et al., 2005) and European Cardiac Society (Task Force for the Diagnosis and Treatment of Chronic Heart Failure et al., 2005). In March 2000, the NHS published a national service framework (NSF) for coronary heart disease which included a chapter dealing with heart failure (Department of Health, 2000). This specified that “[t]he aims of treating heart failure are to improve quality of life by:

- improving symptoms or slowing their deterioration
- reducing mortality

- reducing the frequency of cardiac events and admissions to hospital
- avoiding adverse effects from treatment
- improving the end-of-life experience for both patients and carers.”

Following on from the NSF, the National Institute for Clinical Excellence (NICE) published guidelines for the management of heart failure in July 2003 (National Institute for Clinical Excellence., 2003).

When this study began in February 2001, earlier editions of these guidelines were available. The most up to date guidelines available at that time were those of the Scottish Intercollegiate Guidelines Network (1999). Although the guidelines have been updated since the study began, current recommendations are outlined here as procedures for providing optimised medical care for heart failure at the study hospital would have met with these guidelines. The only exception would have been the time of initiation of beta-blocker therapy (see below) which became more frequently prescribed earlier in treatment. Recommendations for the treatment of heart failure according to current guidelines are set out below:

### **2.5.1 Pharmacological treatment**

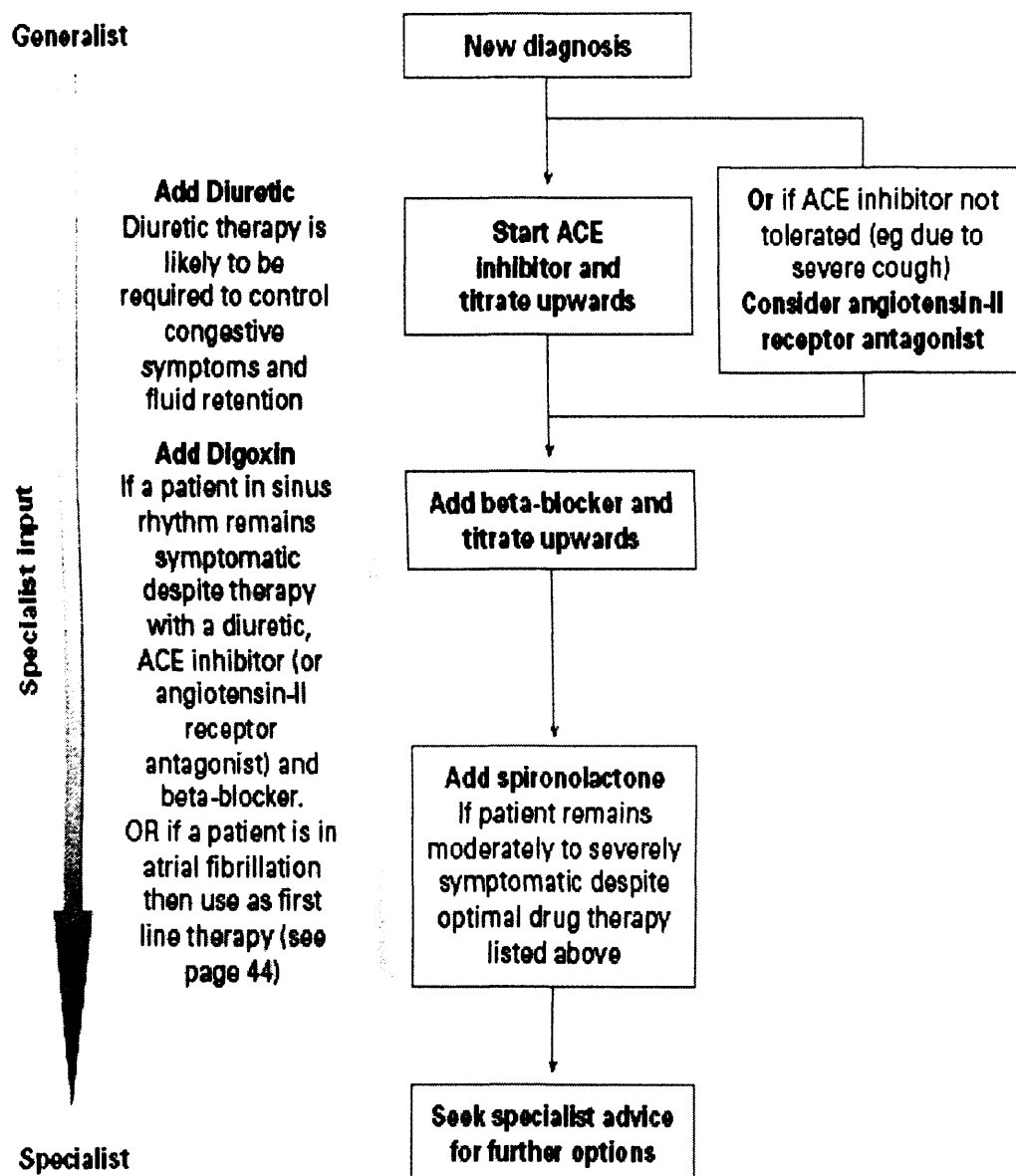
Medication forms the basis of the medical treatment for heart failure due to left ventricular systolic dysfunction, particularly diuretics, ACE inhibitors, beta-blockers and spironolactone. A treatment algorithm for patients with heart failure and reduced left-ventricular systolic function is shown in Figure 2.4.

Diuretics are one of the main treatments for heart failure and are prescribed to almost all symptomatic patients (Faris, Purcell, Henein, & Coats, 2002; National Institute for Clinical Excellence., 2003). They help the kidneys to eliminate excess water and sodium thus reducing the workload of the heart by decreasing blood volume.

Angiotensin-converting enzyme (ACE) inhibitors dilate blood vessels making it easier for the heart to pump blood. They reduce retention of salt and water and protect the heart's left ventricle from becoming more enlarged and inefficient. ACE inhibitors have been shown to reduce admissions to hospital and mortality and are recommended for all patients with systolic heart failure (CONSENSUS Trial Study Group, 1987; Garg & Yusuf, 1995; SOLVD Investigators, 1992; National Institute for Clinical Excellence., 2003).

Beta-blockers are a more recent addition to heart failure therapy. They slow the heart and make it beat less strongly and, by a range of only partially understood mechanisms, improve left ventricular function and thereby reduce symptoms of shortness of breath and fatigue. The addition of a beta-blocker to heart failure therapy has been found to further reduce admissions to hospital and mortality. (Packer, Coats, Fowler et al, 2001; Beta-Blocker Evaluation of Survival Trial Investigators, 2001; Brophy, Joseph, & Rouleau, 2001; Whorlow & Krum, 2000; Packer, Fowler, Roecker et al., 2002). The combination of ACE inhibitor and beta-blocker has been described as the cornerstone of treatment of left-ventricular systolic dysfunction (McMurray & Pfeffer, 2005) and NICE guidelines recommend the initiation of beta-blockers for heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy. Initially beta-blockers were not recommended for patients who have co-morbid respiratory disorders but this situation is changing.

**Fig 2.4 Algorithm for the pharmacological treatment of symptomatic heart failure due to LV systolic dysfunction. (NICE Guideline 2003)**



If patients remain moderately or severely symptomatic after treatment with the foregoing medications, the addition of spironolactone is recommended (National

Institute for Clinical Excellence., 2003; Pitt, Zannad, Remme et al, 1999). This is an aldosterone receptor antagonist which is recommended because aldosterone encourages the body to release adrenaline and noradrenaline, making the heart beat faster and more strongly and raising blood pressure. The RALES study (Pitt et al, 1999) showed that addition of low-dose spironolactone to diuretic and ACE inhibitor therapy improved survival in patients in advanced heart failure. The order in which this medication is added to treatment will however be modified by the clinical picture.

Many patients with heart failure are likely to be prescribed other additional medications, which may include treatments for angina, hypertension and atrial fibrillation. Other common co-morbid conditions include diabetes, respiratory disease and arthritis (Krum & Gilbert, 2003; Zhang, Rathouz, & Chin, 2003) which also require additional medications.

It can be seen that the medication regime of patients with heart failure is complicated, often including several medications both for heart failure and for co-morbid conditions. This is confirmed by the EuroHeart Failure Survey, conducted in 2000-2001, which screened discharge summaries of 11304 patients hospitalised for heart failure in 24 countries, and found that 44.6% of the population used four or more different drugs (Komajda, Follath, Swedberg et al., 2003).

### **2.5.2 Devices and Surgery**

Implantable devices that have been found to improve outcomes for some patients with heart failure include an implantable cardiac defibrillator and cardiac resynchronisation therapy. Patients with heart failure are at risk of sudden death due to ventricular arrhythmias but the SCD-HeFT study found that an implantable cardiac defibrillator



reduced the risk of death by 23% (Bardy, Lee, Mark et al., 2005). In about 25% of patients with heart failure, there is dyssynchronous contraction between the walls of the left ventricle, caused by abnormal electrical activation. Dyssynchrony may exacerbate cardiac dysfunction and further reduce cardiac output. Cardiac resynchronisation therapy has been shown to reduce the risk of death or hospital admission in this group of patients by 37% (Cleland, Daubert, Erdmann et al., 2005).

Heart transplantation is the treatment of last resort which is suitable for selected patients but severely restricted by the limited availability of donor hearts. Controlled trials of transplantation have not been performed but recent studies have shown 5-year survival of 70-80%. Ventricular assist devices have been used while patients have been awaiting transplantation and there is increasing interest in their use as a long-term treatment (Park, Tector, Piccioni et al., 2005).

In practice, implantable devices and surgery are suitable only for a fairly small number of highly selected patients and medication remains the mainstay of medical treatment for heart failure.

### **2.5.3 Other aspects of non-pharmacological management**

In addition to taking prescribed medication, a number of non-pharmacological measures are also recommended in the guidelines referred to above. Most have not undergone randomised controlled trials but are recommended by consensus of experts. The guidelines provided by the European Society of Cardiology are described below as they are the most detailed on this area of management (Task Force for the Diagnosis and Treatment of Chronic Heart Failure, 2001; Task Force for the Diagnosis and Treatment of Chronic Heart Failure et al., 2005).

### 2.5.3.1 General advice

It is recommended that patients with heart failure and their close relatives should receive general advice about topics set out in Table 2.2

**Table 2.2 List of subjects to discuss with a heart failure patient and his family**

General advice
<ul style="list-style-type: none"><li>• Explain what heart failure is and why symptoms occur</li><li>• Causes of heart failure</li><li>• How to recognize symptoms</li><li>• What to do if symptoms occur</li><li>• Self-weighing</li><li>• Rationale of treatments</li><li>• Importance of adhering to pharmacological and non-pharmacological prescriptions</li><li>• Refrain from smoking</li><li>• Prognosis</li></ul>
Drug counselling
<ul style="list-style-type: none"><li>• Effects</li><li>• Dose and time of administration</li><li>• Side effects and adverse effects</li><li>• Signs of intoxication</li><li>• What to do in case of skipped doses</li><li>• Self-management</li></ul>
Rest and exercise
<ul style="list-style-type: none"><li>• Rest</li><li>• Exercise and activities related to work</li><li>• Daily physical activity</li><li>• Sexual activity</li><li>• Rehabilitation</li></ul>
Vaccinations
Travel
Dietary and social habits
<ul style="list-style-type: none"><li>• Control sodium intake when necessary i.e. some patients with severe heart failure</li><li>• Avoid excessive fluids in severe HF</li><li>• Avoid excessive alcohol intake</li></ul>

From: European Heart Journal, 2001;22:1538, updated 2005 [www.escardio.org](http://www.escardio.org)

### 2.5.3.2 Weight control

One of the early signs of deteriorating heart failure is rapid weight gain caused by fluid retention, therefore patients are advised to weigh themselves on a regular basis. In the event of sudden unexpected weight gain of more than 2kg in 3 days it is recommended that they alert a health care professional or adjust their diuretic dose accordingly.

#### **2.5.3.3 Dietary measures**

Patients with advanced heart failure are advised to control their sodium intake. No studies have been conducted to evaluate specific recommendations for sodium restriction but 2g per day is frequently recommended. If this is unpalatable, a 3g diet may be a more realistic target which can be achieved by avoiding convenience foods and not adding salt to food (Grady, Dracup, Kennedy et al., 2000). Patients with advanced heart failure are also advised to restrict their fluid intake. The optimum fluid intake is unclear but 1.5 to 2 litres per day is advised. Moderate alcohol intake is permitted except in the case of patients whose heart failure is due to alcoholic cardiomyopathy, in which case alcohol consumption is contraindicated.

#### **2.5.3.4 Obesity**

The ESC recommends that treatment of chronic heart failure should include weight reduction if the patient is overweight (body mass index between 25 and 30) or obese (body mass index >30).

#### **2.5.3.5 Abnormal weight loss**

Up to 50% of heart failure patients may have some degree of malnutrition (Carr, Stevenson, Walden, & Heber, 1989). Cardiac cachexia (the wasting of body fat and lean body mass that accompanies weight loss) is a predictor of reduced survival. Patients may reduce their food intake because of feelings of nausea, breathlessness or feeling bloated so are advised to take small frequent meals. Increasing muscle mass by taking adequate physical activity is also recommended.

#### **2.5.3.6 Smoking**

Smoking should be discouraged and use of smoking cessation aids are widely encouraged (although this is on the basis of good health grounds rather than evidence developed from the heart failure population).

#### **2.5.3.7 Travelling**

Patients should be discouraged from travelling to locations of high altitudes or that are very hot or humid. Patients also need to be cautioned about the risks of long air flights i.e. dehydration, peripheral oedema and deep vein thrombosis

#### **2.5.3.8 Sexual activity**

Recommendations are to reassure those patients who are not severely compromised but are concerned about the risk of cardiac decompensation triggered by sexual activity.

#### **2.5.3.9 Advice on immunisations**

Immunisation against influenza and pneumococcal infection is also recommended as these infections can precipitate worsening of cardiac function and lead to hospital admission.

#### **2.5.3.10 Drug counselling**

Patients should be given information about the expected effects and side-effects of their medications and advice about drugs to avoid when prescribed heart failure medication. Self-adjustment of diuretics based on changes in symptoms and fluid balance should be encouraged when practical.

#### **2.5.3.11 Rest and exercise**

Rest is advised in acute or decompensated heart failure but as the patient's condition improves, active mobilisation should be carried out. If patients are in a stable condition, they are encouraged to carry out usual daily physical and leisure activities that do not

induce symptoms. Exercise training is encouraged in stable patients in NYHA II and III. Randomised trials have shown that regular exercise can safely improve peak oxygen uptake and strength (McKelvie, Teo, Roberts et al, 2002) and can improve symptoms (Corvera-Tindel, Doering, Woo et al, 2004) and quality of life and reduce mortality (Belardinelli, Georgiou, Cianci, & Purcaro, 1999).

## **2.6 Shortcomings in the diagnosis and management of heart failure**

It is widely recognised that in the past, the diagnosis and management of heart failure have been suboptimal (Feenstra, Grobbee, Jonkman, Hoes, & Stricker, 1998; McDonald, 2005; Hunt et al., 2002).

### **2.6.1 Shortcomings in the diagnosis of heart failure**

Receipt of the correct diagnosis is essential for the initiation of appropriate treatment. Heart failure is recognised as being difficult to diagnose clinically as the principal symptoms (breathlessness) and signs (peripheral oedema) are non-specific and therefore could be due to other conditions (Task Force for the Diagnosis and Treatment of Chronic Heart Failure, 2001). Other signs that are more specific, such as raised jugular venous pressure and a third heart sound are less common and more difficult to detect. Investigation to confirm the diagnosis is therefore required. European Society of Cardiology guidelines recommend that patients with suspected heart failure have an electrocardiogram (ECG), chest X-ray, laboratory investigations of haematology and biochemistry and an echocardiogram (Task Force for the Diagnosis and Treatment of Chronic Heart Failure, 2001). The ECG examines cardiac rhythm, rate and conduction and, if normal, suggests that a diagnosis of heart failure is unlikely. The chest X-ray can be useful in identifying pulmonary oedema and to exclude pulmonary disease. Haematology and biochemistry can identify other conditions that can co-exist with or

complicate heart failure such as renal disease and diabetes. A diagnosis of heart failure requires objective evidence of cardiac dysfunction at rest and the echocardiogram is used for this purpose. Each of these investigations provides diagnostic information and also helps to guide treatment (McMurray & Pfeffer, 2005).

The EuroHeart Failure survey programme (Cleland et al., 2003) found that in 2000-2001, of patients admitted to hospital with heart failure, over 90% had an ECG, chest X-ray and measurement of haemoglobin and electrolytes but only 66% overall, and only 56% in the UK, had ever had an echocardiogram. This represents a considerable deficiency compared to European Society of Cardiology (ESC) guidelines and highlights the requirement for improvement in the diagnosis of heart failure. The importance of diagnostic investigations was shown by Polanczyk, Newton, Dec, & Di Salvo (2001) who found that, in patients discharged from hospital with a diagnosis of heart failure, those patients with unknown ejection fraction or suspected valve disease who did not have an echocardiogram were more likely to be readmitted to hospital within 90 days.

### **2.6.2 Shortcomings in the implementation of pharmacological treatment**

The MAHLER study evaluated the impact of implementation or non-implementation of ESC treatment guidelines from November 2001 to September 2002 in six European countries (France, Germany, Italy, The Netherlands, Spain, UK). Cardiovascular and heart failure hospitalisation were significantly lower in groups with better adherence to guidelines for prescription of ACE inhibitors, beta-blockers and spironolactone (Komajda, Lapuerta, Hermans et al., 2005). Polanczyk, Newton, Dec & DiSalvo (2001) found that patients who were not treated with ACE inhibitors on discharge from hospital were more likely to be readmitted within the following 90 days.

Data from General Practice in England and Wales showed that in 1998, 91.1% of men and 93.5% of women with heart failure were prescribed diuretics but only 53.1% and 43.6% respectively were prescribed an ACE inhibitor. Beta-blockers are a more recent addition to recommended treatment (see above) and in 1998 they were prescribed to only 10.6% of men and 11.4% of women with heart failure (Ellis, Gnani, & Majeed, 2001). The EuroHeart Failure Survey (Komajda et al., 2003) found that in 2000-2001, 86.9% of patients hospitalised for heart failure were prescribed diuretics, 61.8% were prescribed ACE inhibitors, 36.9% were prescribed beta-blockers and 20.5% were prescribed spironolactone. Only 17.2% received the combination of diuretic, ACE inhibitors and beta-blockers.

As well as under-prescription of recommended medications, incorrect prescription has also been identified as contributing to unplanned hospital admission. For example, Ghali et al 1988 considered inadequately conceived drug therapy to have contributed to hospital admission in 17% of cases (Ghali, Kadakia, Cooper, & Ferlinz, 1988). Opasich, Febo, Riccardi et al, 1996 followed up 304 patients who had been referred to them for assessment for transplant. During the mean follow-up period of 310 days, 161 patients had a total of 328 nonfatal decompensations. Iatrogenic factors were considered to have contributed to 33 (10%) and were mostly associated with inadequate medical treatment, particularly withdrawal of ACE inhibitors and/or excessive doses of diuretics (Opasich et al., 1996). Vinson, Rich, Sperry, Shah & McNamara, 1990) reported that 7/66 (11%) of the readmissions they examined were due to dehydration, most probably caused by excessive diuretic use. Iatrogenic factors, defined as heart failure precipitated by medications or excessive fluid administration, were also considered to have been responsible for 7% of admissions in a study by Rich (1996) who examined precipitating factors leading to hospital admission in 401 patients 70 years of age or older hospitalized with congestive heart failure.

Tsuyuki, McKelvie, Arnold et al (2001) prospectively explored the immediate precipitants associated with exacerbation of CHF in patients enrolled in a 43-week multi-centre clinical trial. Use of calcium channel blockers (a medication not recommended in heart failure due to systolic dysfunction and contra-indicated in addition to beta-blockade) were identified as the cause of exacerbation in 13% of cases and inappropriate reductions in CHF therapy in 10% of cases.

These findings highlight both the benefits of optimising prescription of recommended medications and the room for improvement in pharmacological management of heart failure.

### **2.6.3 Early discharge and inadequate follow-up**

The relationship between premature hospital discharge and risk of unplanned readmission has been known for some time. For example, Ashton, Kuykendall, Johnson, Wray, & Wu (1995) assessed quality of inpatient care of 2513 male inpatients, 748 of whom had a diagnosis of heart failure, and the relation to unplanned readmission within 14 days of discharge. They reported that in patients with heart failure, lower adherence by clinicians to 'readiness-for-discharge criteria', which included ensuring that patients were clinically stable, was associated with an increased risk of readmission. It was considered that 1 in 5 readmissions in patients with heart failure were attributable to substandard care.

In contrast, when McDonald, Ledwidge, Cahill et al (2001) optimised in-patient care for all patients with heart failure and ensured that they were not discharged until clinically stable and on the target dose of ACE inhibitor, no patients in either the optimised standard care control group or the intervention group (who received additional



telephone and clinic follow-up) were readmitted to hospital within one month of discharge. This compared to a readmission rate of 20% before instigation of this management plan. This study demonstrates the importance of discharging patients from hospital only when they are clinically stable and on optimal treatment.

Patients with heart failure can deteriorate rapidly as evidenced by the high rate of unplanned readmissions within a short period after discharge from hospital. Haphazard follow-up after discharge has been identified as another factor contributing to unplanned readmission (Moser & Mann, 2002). Vinson, Rich, Sperry et al (1990) considered that inadequate follow-up (as evidenced by failure to involve home care and/or prolonged time to next physician appointment) contributed to preventable readmissions in 20% of cases. When Tsuchihashi, Tsutsui, Kodama et al (2001) followed 230 patients for 1 year after discharge from hospital with a diagnosis of heart failure, they found that patients who had  $\leq 1$  follow-up clinic visit per month were at greater risk of readmission (odds ratio 4.9, 95% CI 2.0-11.8).

Patients who participated in focus groups in the UK for the development of the NICE guidelines reported that once discharged from the care of a consultant they could fall out of the system and find it difficult to access care easily if they deteriorated (National Institute for Clinical Excellence, 2003). The NICE guidelines recommend that “frequency of monitoring should depend on the clinical status and stability of the patient. Monitoring interval should be short (days to two weeks) if the clinical condition or medication has changed, but is required at least six-monthly for stable patients”.

#### **2.6.4 Shortcomings in patient self-management**

Living with heart failure requires patients to undertake many different tasks to manage their illness, such as taking medication and making dietary changes, amongst others.

Behaviours such as these, which rely on the patient taking an active role in their illness, may be considered part of self-management, which will be described in greater detail in the next chapter. Shortcomings in the way patients manage their illness are considered to contribute to poor outcomes in heart failure. These shortcomings include non-adherence to medication and other aspects of the recommended treatment regime and failure to identify and act upon early signs of worsening heart failure.

#### **2.6.4.1 Practice of self-management behaviours**

##### *2.6.4.1.1 Taking medication*

Studies that have measured adherence to medication in heart failure have reported rates that vary from 10% to over 90% but most are between 70-85% (van der Wal, Jaarsma, & van Veldhuisen, 2005). Studies have used different methods to assess medication adherence, including patient self-report, pill counts, prescription refills and electronic event monitoring, which records when medication bottles are opened and closed. Differing reported rates of adherence may be partly explained by these different methods and also by different ways of defining adherence. For example, in an early study, Monane, Bohn, Gurwitz, Glynn, & Avorn (1994) assessed how many times a sample of 7247 patients refilled prescriptions for digoxin over a 12 month period and found that only 10% filled them often enough to have sufficient medication for the 12 month period. In contrast, Welsh, Heiser, Schooler et al (2002) found that 79% of patients attending the emergency department for heart failure reported not having deviated from their prescribed regimen. This study used patient interviews to assess adherence but a similar rate was found by Bohachick, Burke, Sereika, Murali, & Dunbar-Jacob (2002) who assessed adherence to ACE inhibitors over a 3 month period using electronic event monitoring and found that 71% of patients took 85-100% of the prescribed dose. Nevertheless, 19% of patients took less than 70% of the prescribed dose and the rate of adherence was also found to vary by the number of daily prescribed doses – adherence rates of 90%, 84% and 68% were reported for

medications prescribed once, twice or three to four times a day, respectively. Adherence to medication may also decline over time. Butler, Arbogast, Daugherty et al (2004) compared ACE inhibitor use in the 30 days and 12 months after discharge from hospital and found that, of those patients discharged on an ACE inhibitor, 77.1% had filled a prescription within 30 days and only 63.3% had a current prescription i.e. filled in the prior 30 days, at 12 months.

Although reported rates of medication adherence may vary, these studies indicate that it is often sub-optimal and may be influenced by factors such as the daily regime and the duration for which a patient has been taking the medication.

#### *2.6.4.1.2 Diet and exercise*

Performance of other recommended self-management behaviours may be even lower. When Hershberger, Ni, Nauman et al (2001) assessed self-management behaviour of patients attending an out-patient management programme, at baseline 80.9% of patients reported taking their medication as prescribed all the time but only 47.2% reported avoiding salty foods, even though 75.3% reported being aware of the need for salt restriction. Other studies have found the percentage of patients restricting their sodium intake to vary from 43% to 88% (van der Wal et al., 2005). Few studies have examined practise of fluid restriction but those which have suggest that it is fairly uncommon. Artinian, Magnan, Sloan, & Lange (2002) reported monitoring of fluid intake to be one of the least frequently performed of the self-management behaviours they measured. Jaarsma, Abu Saad, Dracup, & Halfens, (2000) reported that only 23% of patients adhered to fluid guidelines and Ni, Nauman, Burgess et al (1999) found that over one third of patients thought they should drink lots of fluids. Other lifestyle changes, particularly regarding physical activity, are also not adopted by many patients. The review by van der Wal et al (2005) reported that between 41-58% of patients did not follow recommendations regarding activity and rest.

#### *2.6.4.1.3 Self-monitoring*

Heart failure can deteriorate rapidly making it essential to identify early signs of problems so that immediate remedial action can be taken. It would appear, however, that many patients do not monitor for signs of deterioration and when symptoms become worse they often delay before seeking medical help. The review by van der Wal et al (2005) identified 8 studies that examined adherence to daily weighing and found that rates ranged from 12% to 75% but most were under 50%. Furthermore, those patients who do monitor their weight do not necessarily contact a health care professional when their weight increases (Jaarsma, Abu Saad, Dracup et al, 2000) or when they experience other symptoms of worsening heart failure. In a study of 181 older adults admitted for heart failure, Friedman (1997) found that 91% reported having dyspnoea for an average of 3 days and 35% had oedema for an average of 7 days before hospital admission. On admission, only 5% reported weight gain as a symptom, suggesting that most patients had not been monitoring their weight nor recognised weight gain to be an indicator of deterioration. Another study (Evangelista, Dracup, & Doering, 2000) found that 28% of patients waited more than 5 days before seeking medical attention for symptoms of heart failure. Artinian et al (2002) examined heart failure self-care behaviour in 110 patients and found that the least frequently performed behaviours related to self-monitoring and to contacting health care professionals in response to signs of exacerbation.

#### **2.6.4.2 Implications of shortcomings in self-management**

It is apparent from the above examples that a significant proportion of people with heart failure do not follow self-management recommendations and a number of studies have suggested that these shortcomings contribute to poor outcomes.

Eleven studies published between 1988 and 2002 (van der Wal et al., 2005) considered non-adherence to medication or diet to have contributed to worsening heart

failure in between 15% to 64% of cases. For example, Michalsen, Konig, & Thimme (1998) asked 179 patients admitted to hospital for heart failure about their daily fluid and salt intake and adherence to prescribed medication. Patients were classified as 'non-compliant' if they reported taking their medication intermittently or not at all, if their fluid intake was more than 2.5 litres per day or if they regularly added salt to their food. In this study, 43% of patients reported excess sodium intake, 34% reported excess fluid intake and 23.5% reported poor adherence to medication. Potential factors precipitating the hospital admission were identified in 85.5% of the study sample and non-adherence to medication or diet (excessive sodium or fluid intake) was the leading precipitating factor for hospital admission, considered to have caused 41.9% of cases.

Delay in seeking medical attention in response to early signs and symptoms of worsening heart failure is also considered to contribute to unplanned hospital admissions. The studies outlined above showed that many patients wait several days before seeking attention in which time remedial action, which may have prevented further deterioration, could have been taken. In an examination of 161 patients admitted to hospital for heart failure, Vinson, Rich, Sperry et al (1990) considered that failure to seek medical attention promptly when symptoms recurred contributed to 20% of the hospital readmissions they classified as preventable.

Unfortunately these studies have examined precipitants of worsening heart failure retrospectively and the assessment of self-management behaviours was usually poorly defined. Prospective examination of the impact of self-management behaviours on outcomes therefore remains necessary although difficult to perform. Nevertheless, the identification of shortcomings in self-management as a precipitating factor in several studies suggests that self-management behaviours appear to be an important target for intervention.

### 2.6.5 Rectifying shortcomings in management of heart failure - disease management programmes

The organisation of medical care provision for patients with heart failure has undergone considerable change in many countries over recent years. Probably the most widely adopted approach has been the introduction of disease management programmes which aim to address the shortcomings described above in medical management and patient self-management. There is considerable variation in these programmes but they typically consist of one or more of, medication review and optimisation of therapy, discharge planning i.e. assessing patients' post discharge needs, coordinating primary and secondary care, specialist follow-up and education about heart failure, its treatment and identification of early signs of deterioration. The programmes also vary across several other parameters, as shown in Table 2.3.

**Table 2.3. Variability in disease management programmes**

<b>Study variable</b>	<b>Variation between studies</b>
Patient selection	Many exclusion criteria are fairly consistent across studies, such as exclusion of patients with a psychiatric or terminal illness, but in addition some studies limit patient selection by factors such as age, heart failure severity and risk of readmission
Recruitment	Most, but not all, programmes are targeted at patients admitted to hospital as this group is known to be at high risk of readmission and death
Time of intervention delivery	Interventions vary in whether they commence during the index hospital admission, at the time of discharge or shortly after discharge
Place of intervention delivery	Interventions are delivered in primary care, outpatient clinics, the patient's home, over the telephone or a combination of these
Professional(s) delivering the intervention	Most interventions are led by a nurse working under the guidance of a cardiologist but a small number are multidisciplinary, including one or more of pharmacists, dieticians, psychologists, physiotherapists and social workers
Intervention duration	Interventions vary from a single session to a series of visits and telephone calls over a year
Background 'standard' care	What constitutes 'standard care' varies considerably between studies, reflecting the differences in care that exist between different hospitals and between different health care systems. Studies have been conducted in the US, Canada, Europe, Australia and New Zealand

### **2.6.5.1 Efficacy of disease management programmes**

Several reviews of heart failure disease management programmes have been performed (Philbin, 1999; Rich, 1999; McAlister, Lawson, Teo, & Armstrong, 2001; Windham, Bennett, & Gottlieb, 2003; Gonseth, Guallar-Castillon, Banegas, & Rodriguez-Artalejo, 2004; Gustafsson & Arnold, 2004; Gwady-Sridhar, Flintoft, Lee, Lee, & Guyatt, 2004; McAlister, Stewart, Ferrua, & McMurray, 2004; Bruggink-Andre-de-la-Porte, Lok, van Wijngaarden et al., 2005; Phillips, Singa, Rubin, & Jaarsma, 2005; Roccaforte, Demers, Baldassarre, Teo, & Yusuf, 2005; Whellan, Hasselblad, Peterson, O'Connor, & Schulman, 2005; Holland, Battersby, Harvey et al., 2005; Phillips et al., 2004; Yu, Thompson, & Lee, 2006), and their main findings are summarised in Table 2.4. Those reviews which combined the studies in meta-analyses concluded that disease management programmes have been successful in reducing hospitalisation among patients with heart failure. However, the reviews also highlight that there is considerable heterogeneity in the findings. For example, in the review by McAlister et al., (2004), a significant reduction in all-cause hospitalisation for the combined sample was reported (a summary risk ratio of 0.84) but the risk ratios in individual studies ranged from 0.15 to 1.26. The programmes were also successful in reducing hospital admissions for heart failure (summary risk ratio of 0.73, but again, there was considerable heterogeneity in the findings). Few programmes produced reductions in mortality.

#### ***2.6.5.1.1 Component efficacy***

The heterogeneity of study findings raises questions about which components, or combinations of components, of these complex interventions are most important to achieve improved outcomes. Some of the reviews described above have examined this issue but they have not been able to identify the underlying mechanism for improved

outcomes of disease management programmes (Whellan et al, 2005) nor the most effective model of disease management (Gonseth et al, 2004).



**Table 2.4 Summary of reviews of disease management programmes for heart failure.**

Review	Aim of review	Number of studies	Findings
Philbin 1999	To evaluate the impact of programmes on process of care, resource utilisation, health care costs and clinical outcomes	7 controlled trials published 1995 - 1998	<ul style="list-style-type: none"> <li>• 6/7 studies reported reductions in hospital readmission rates in the intervention group, ranging from 50 – 74%</li> <li>• 3 studies that examined costs reported a reduction in costs in the intervention group</li> <li>• 4/4 studies reported improvements in functional status</li> <li>• 1/2 studies reported improved QoL</li> </ul>
Rich 1999	To evaluate current status of HF disease management	6 randomised controlled trials and 10 non-randomised trials published 1983 - 1998	<p>Of the randomised trials:</p> <ul style="list-style-type: none"> <li>• 5 studies - Reductions in hospital admissions ranged from 27% to 73%</li> <li>• 2 studies - Reductions in hospital days of 25% and 43%</li> <li>• 2 studies – lower hospital costs</li> <li>• 1 study – better QoL</li> </ul>
McAlister et al 2001	To examine whether programmes reduce mortality or hospitalisation rates	11 randomised controlled trials published 1993 - 1999	<p>In meta-analysis:</p> <ul style="list-style-type: none"> <li>• 7 studies – no significant reduction in mortality (pooled RR 0.94, 95% CI 0.75 – 1.19)</li> <li>• 11 studies – significant reduction in readmission (pooled RR 0.87, 95% CI 0.9 – 0.96)</li> <li>• 7/8 studies reported fewer total hospitalisations in the intervention group</li> <li>• 7/9 studies reported shorter length of stay or reduced total hospital days in the intervention group</li> <li>• 1/5 studies reported better QoL in the intervention group</li> <li>• 7/8 studies reported cost savings in the intervention group</li> </ul>

Review	Aim of review	Number of studies	Findings
Windham et al 2003	To define the components of successful care management	15 randomised controlled trials, 17 non-randomised trials published 1971 – 2002	In the randomised controlled trials : <ul style="list-style-type: none"> <li>• 6/14 reported significantly fewer admissions in the intervention group</li> <li>• 0/9 reported lower mortality</li> <li>• 2/7 reported better QoL in the intervention group</li> <li>• 2/5 reported fewer emergency visits in the intervention group</li> <li>• 3/9 reported lower costs in the intervention group</li> </ul>
Gonseth et al 2004	Review effectiveness of disease management programmes in reducing hospital admissions	27 randomised controlled trials and 27 non-randomised trials published 1993 - 2003	In meta-analysis of randomised trials: <ul style="list-style-type: none"> <li>• 11 studies examined readmission for HF or other cardiovascular disease – significantly reduced risk of readmission in intervention group (pooled RR 0.70, 95% confidence interval (CI) 0.62 – 0.79)</li> <li>• 16 studies examined all-cause readmission – significantly reduced risk of readmission in intervention group (pooled RR 0.88, 95% CI 0.79 – 0.97)</li> <li>• 10 studies examined combined outcome of death or all-cause readmission – significantly reduced risk of event in intervention group (pooled RR 0.82 95% CI 0.72 – 0.94)</li> </ul>
Gustafsson et al 2004	To describe and critically evaluate HF clinics using nurse intervention	18 randomised controlled trials published 1993 - 2003	<ul style="list-style-type: none"> <li>• No clear overall reduction in mortality</li> <li>• 8/18 studies reported significant reductions in hospital readmission rates</li> </ul>
Gwadry-Sridhar et al 2004	To evaluate the effectiveness of HF programmes on hospital readmission rates	8 randomised controlled trials published 1993 - 2001	<ul style="list-style-type: none"> <li>• Pooled RR for readmission was 0.79, 95% CI 0.68 – 0.91 favouring the intervention group</li> <li>• Pooled RR of mortality was not significant (RR 0.98, 95% CI 0.72 – 1.34)</li> <li>• 2/3 studies reported a significant improvement in QoL in the intervention group</li> </ul>

Review	Aim of review	Number of studies	Findings
McAlister et al 2004	To examine whether programmes improve outcomes	29 randomised controlled trials published 1993 – 2004	<ul style="list-style-type: none"> <li>• 2/22 studies reported significant reduction in mortality in the intervention group (pooled RR 0.83, 95% CI 0.70 – 0.99)</li> <li>• 3/22 studies reported a significant reduction in all-cause hospitalisation rate in the intervention group (pooled RR 0.84, 95% CI 0.75 – 0.93)</li> <li>• 6/19 studies reported a significant reduction in heart failure hospitalisation rate in the intervention group (pooled RR 0.73, 95% CI 0.66 – 0.82)</li> <li>• 11/21 studies reported significantly fewer total hospitalisations in the intervention group (pooled RR 0.70, 85% CI 0.62 – 0.80)</li> <li>• There was also a reduction in total HF hospitalisations but the number of studies is unclear in the review (pooled RR 0.57, 95% CI 0.49 – 0.67)</li> <li>• 9/18 studies reported significantly better QoL in the intervention group</li> <li>• 15/18 studies reported that the intervention was cost saving</li> </ul>
Phillips et al 2004	To evaluate the impact of programmes on hospital admissions, length of stay, mortality, QoL, costs	18 randomised controlled trials published 1993 - 2003	<p>In meta-analysis:</p> <ul style="list-style-type: none"> <li>• 18 studies - significant reduction in all-cause admission (pooled RR 0.75, 95% CI 0.64 – 0.88)</li> <li>• 14 studies – no significant reduction in mortality (pooled RR 0.87, 95% CI 0.73 – 1.03)</li> <li>• 10 studies – no significant reduction in mean length of stay (Pooled reduction -0.37, 95% CI -0.15 – 0.60)</li> <li>• 3/6 studies reported better QoL in the intervention group</li> <li>• Pooled cost savings were significant for US studies but not non-US studies</li> </ul>

Review	Aim of review	Number of studies	Findings
Bruggink-Andre de la Porte 2005	To discuss the applicability of HF management programmes in countries with well structured primary care	21 randomised controlled trials published 1995 - 2003	<ul style="list-style-type: none"> <li>• 5/9 studies reported a significant reduction in the combined endpoint of death or all-cause hospital readmission</li> <li>• 2/5 studies reported a significant reduction in the combined endpoint of death or HF hospital readmission</li> <li>• 7/18 studies reported a significant reduction in all-cause readmission rate</li> <li>• 5/9 studies reported a significant reduction in HF readmission rate</li> <li>• 5/15 studies reported a significant reduction in days spent in hospital</li> <li>• 1/14 studies reported a significant reduction in mortality</li> <li>• 4/13 studies reported significant improvement in QoL</li> <li>• 2/2 studies reported significant improvement in self-care</li> <li>• 3/14 studies reported significant cost savings</li> </ul>
Holland et al 2005	To examine the impact of programmes on hospital admission and mortality	30 randomised controlled trials published 1995 - 2005	<p>In meta-analysis:</p> <ul style="list-style-type: none"> <li>• 21 studies - significant reduction in all-cause admission (pooled RR 0.87, 95% CI 0.79 – 0.95)</li> <li>• 27 studies – significant reduction in mortality (pooled RR 0.79, 95% CI 0.69 to 0.92)</li> <li>• 16 studies – significant reduction in HF admission (pooled RR 0.70, 95% CI 0.61 – 0.81)</li> <li>• 10 studies – significant decrease of hospital days of 1.9 days in favour of intervention group (95% CI 0.71 – 3.1)</li> </ul>

Review	Aim of review	Number of studies	Findings
Phillips et al 2005	To study the effectiveness of programmes incorporating nurse-led clinics in relation to the intervention complexity	6 randomised controlled trials published 1998 - 2003	In meta-analysis: <ul style="list-style-type: none"> <li>• 6 studies – no significant difference in all-cause admission (pooled RR 0.91, 95% CI 0.72 – 1.16)</li> <li>• 6 studies – no significant difference in mortality (pooled RR 0.80, 95% CI 0.57 – 1.06)</li> <li>• 5 studies – no significant difference in QoL</li> <li>• 3 studies – no significant difference in costs</li> </ul>
Roccaforte et al 2005	To summarise evidence of effectiveness of disease management programmes in improving clinical outcomes	33 randomised controlled trials published 1993 - 2004	In meta-analysis: <ul style="list-style-type: none"> <li>• 28 studies – significant reduction in mortality (pooled RR 0.84, 95% CI 0.74 – 0.94)</li> <li>• 32 studies – significant reduction in all-cause hospitalisation rate (pooled RR 0.86, 95% CI 0.82 – 0.91)</li> <li>• 20 studies – significant reduction in HF hospitalisation rate (pooled RR 0.69, 95% CI 0.63 – 0.77)</li> <li>• 12 studies – significant reduction in all-cause hospital days (Weighted mean difference -1.49, 95% CI -2.03 to -0.95)</li> <li>• 5 studies – significant reduction in all-HF hospital days (WMD -1.25, 95% CI -1.99 to -0.50)</li> </ul>
Whellan et al 2005	To assess the effectiveness of disease management programmes in reducing hospitalisation and mortality	19 randomised controlled trials published 1995 - 2003	<ul style="list-style-type: none"> <li>• Interventions that included clinic follow-up by a cardiologist, home visit or telephone follow-up significantly decreased all-cause hospitalisation but clinic follow-up with primary care practitioner supervision did not decrease hospitalisations.</li> </ul>

Review	Aim of review	Number of studies	Findings
Yu et al 2006	To identify the characteristics of disease management programmes crucial to reducing hospitalisation and/or mortality	21 randomised controlled trials published 1995 - 2004	<ul style="list-style-type: none"> <li>• 12 interventions were 'effective' i.e. had a significant impact on readmission and/or mortality</li> <li>• 11 studies – significant reduction in number of hospital admissions (RR: <math>0.56 \pm 0.14</math>)</li> <li>• 4 studies – significantly reduction in mortality (RR: <math>0.42 \pm 0.22</math>)</li> <li>• 8 studies – significant reduction in combined event rate (RR: <math>0.61 \pm 0.17</math>)</li> <li>• Concluded that an effective programme should be multifaceted, consist of in-hospital phase of care, intensive patient education, self-care supportive strategy, optimisation of medication regimen, ongoing surveillance and management of clinical deterioration. Cardiac nurse and cardiologist should be actively involved and a flexible approach should be adopted to deliver follow-up care.</li> </ul>

In attempting to address the question of which type of programme is most effective, some reviews classified them according to how and where care was provided. However, the reviews used different classifications and did not reach the same conclusion. For example, McAlister et al (2004) concluded that all-cause hospital admission was reduced by multidisciplinary teams and interventions emphasising self-care but not those that were telephone based with primary care follow-up. Holland et al (2005) however, concluded that interventions with a home-based component produced the greatest effect on all-cause readmission to hospital while Whellan et al (2005) found significant reductions in all cause hospital admissions in interventions that consisted of clinic follow-up by a cardiologist, home visit or telephone follow-up.

One shortcoming of the majority of these reviews of disease management programmes in heart failure is that they focussed on where the interventions were delivered (e.g. clinic or home) and by whom, rather than according to the actual content of the programmes. Exceptions are the reviews by Phillips et al (2005) and Yu et al (2006) who examined programmes according to their component parts. Phillips et al (2005) described eleven different components – 1. discharge planning, 2. pre-discharge education, 3. post-discharge education, 4. medication counselling and review, 5. optimisation of ACE inhibitors, 6. self-care behaviour, 7. increased communication between providers, 8. home visit, 9. telephone follow-up, 10. specialist heart failure nurse and 11. heart failure clinics – and classified interventions according to presence or absence of each component. The number of these components contained in the interventions reviewed ranged from 7 to 11. The reviewers concluded that better outcomes were obtained by programmes that included hospital discharge planning and immediate discharge follow-up however the reliability of this finding is limited by the small number of studies ( $n = 6$ ) in the review.

Yu et al (2006) classified programmes according to six different criteria – 1. structure of the care team, 2. inclusion of in-hospital care, with or without discharge planning, 3. education, counselling and supportive self-care strategies, 4. optimisation of medical therapy, 5. attention to deterioration in signs and symptoms, and 6. follow-up care. There was considerable heterogeneity in the programmes and Yu et al compared features of the 12 'effective' studies i.e. those which had a significant impact on readmission and/or mortality, with the 9 ineffective studies. Yu et al (2006) summarised the most common features of effective programmes (see Table 2.4) however there was substantial overlap between the composition of the effective and ineffective studies, for example, all studies included patient education and the majority of both effective and ineffective studies included attention to signs of deterioration.

## **2.7 Summary**

It is clear that management of heart failure by both health care professionals and patients themselves has been suboptimal. Developments to improve care through the introduction of disease management programmes have shown some benefits but the heterogeneity in their content, delivery, control condition and outcomes raises issues that require further consideration.

Reviews have not identified an optimal model of care and it is probably unlikely that a single model of care will equally benefit all patients. An important research question is therefore to examine factors that may predict who will benefit from a particular intervention.

The health care environments in which patients are treated vary considerably and Bruggink-André de la Porte et al (2005) caution that heart failure programmes developed in one health care system should not be uncritically implemented in



countries with a different health care system. The available resources vary between health care systems and this also influences what models of care are achievable. Many of the interventions that have been implemented to date have been fairly intensive but there is no evidence as to their optimal intensity and duration, and a need remains to examine whether less intensive models can produce beneficial outcomes. It is necessary therefore to develop and evaluate models that can provide cost effective benefits for patients in the U.K. National Health Service.

One model that could offer the prospect of achieving benefit without exclusive dependence on intensive follow-up by a health care professional is to improve patients' self-management of their heart failure. Shortcomings in self-management have been identified as a factor contributing to poor outcomes. Although almost all disease management programmes include patient education, it is unclear to what extent they have been effective in enhancing patient self-management.

The next chapter will further examine the role of self-management in heart failure. It will describe the current understanding of factors associated with heart failure self-management and review interventions that have included a component aimed at improving the way patients manage their heart failure.

## **CHAPTER 3**

### **SELF-MANAGEMENT OF HEART FAILURE**

This chapter outlines the theoretical background to self-management and describes factors that have been found to influence self-management in heart failure. The chapter then includes a systematic review of interventions in heart failure. This systematic review examines the extent to which the interventions have adopted a self-management approach and their effect on self-management behaviours and other outcomes.

#### **3.1 Definition and key features of self-management**

Living with a chronic illness requires patients to undertake many different tasks to manage their illness on a day-to-day basis. This may include monitoring physiological markers of changes in the illness, taking medication, changing diet and taking exercise, amongst others. The role that patients play in managing their illness is commonly referred to as self-management, which Barlow, Wright, Sheasby et al, (2002) define as, “the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one’s condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life. Thus, a dynamic and continuous process of self-regulation is established.”

It can be seen from this definition that self-management involves more than adhering to the recommended treatment regimen.

### **3.2 Theoretical foundations**

Self-management of a chronic illness is complex therefore it is not surprising that effective self-management can be difficult to achieve (Newman, Steed, & Mulligan, 2004). It has been shown in other chronic illnesses, such as diabetes, asthma and arthritis, that simply providing people with information about what action they should take to manage their illness, for example to take medication, change their diet or increase their physical activity, is not necessarily sufficient to ensure effective self-management (Coates & Boore, 1996; Riemsma, Kirwan, Taal, & Rasker, 2002; Gibson et al., 2000). The recommended behavioural changes are often not easy to make, or patients may choose not to make them, and a number of health psychology theories help to elucidate the role of cognitive, emotional and social factors in health behaviour. Among these are the Health Belief Model (Becker, 1974; Janz & Becker, 1984), the Theory of Planned Behaviour (Ajzen, 1991), Protection Motivation Theory (Rogers, 1975), the Stress Coping Model (Lazarus & Folkman, 1984), Self-Regulation Theory (Leventhal, Nerenz, & Steele, 1984), Social Cognitive Theory (Bandura, 1977), the Transtheoretical Model (Prochaska & DiClemente, 1984) and the Model of Action Phases (Gollwitzer, 1993). Drawing on these theories can help to facilitate the development of interventions designed to enhance self-management. A discussion of all of these theories is beyond the scope of this thesis but two of the theories that are considered particularly relevant to self-management are outlined below. In addition to theories in health psychology, self-management has drawn on cognitive-behavioural models of behaviour change such as cognitive restructuring, which is a feature of cognitive therapy (Beck, 1976) and problem-solving therapy (D'Zurilla & Goldfried, 1971).

### 3.2.1 Self-regulatory model

Psychological theories of self-regulation propose that human activity is goal-directed and that people regulate their behaviour according to their goals (Karoly, 1993). This applies equally to behaviours directed to managing an illness hence self-management can be seen as a self-regulatory process. Leventhal et al's model (Leventhal et al., 1984; Cameron & Leventhal, 2003) proposes how self-regulatory processes operate when a person is confronted with a chronic illness. According to the model, the way people self-manage is a reflection of how they conceptualise their experience of the illness (Horowitz, Rein & Leventhal, 2004).

Leventhal et al propose that people hold a 'common sense' model of their illness which provides a framework through which they understand and respond to it. This framework, or cognitive representation, is influenced by many factors, including a person's existing knowledge about the illness, and information they receive from health care professionals, the media, family and friends. The illness also generates an emotional response. The coping behaviours (which include self-management behaviours) that people select to manage their illness are influenced by both their cognitive representations and their emotional state. People evaluate how effective their coping behaviours have been in managing the illness and this appraisal can then in turn lead to revision of their illness representations and their behaviours. Self-regulation is thus a dynamic process which involves ongoing appraisal and modulation of behaviour, cognition and emotion.

Leventhal et al have investigated the content of cognitive representations of illness and have identified five key dimensions – *identity* refers to the symptoms that are perceived to be related to the illness, *timeline* refers to the perception of the likely time course of the illness, *cause* refers to the beliefs people hold about what caused their

illness, *consequences* refers to the effect people believe the illness has had on their lives and *cure/control* refers both to how amenable the illness is thought to be to cure or control and the extent to which it is under personal control.

### **3.2.2 Social Cognitive Theory**

One of the most influential psychological models in self-management research is the social cognitive model (Bandura, 1986), particularly the concept of self-efficacy (Bandura, 1997). Self-efficacy is related to the concept of control in the self-regulatory model but is more specific, referring to confidence in one's ability to perform a specific behaviour rather than a more general sense of control over one's illness.

Social cognitive theory proposes that the determinants of behaviour are multifaceted, incorporating both personal and socio-structural factors. According to this model, behaviour is influenced by the goals people have, their expectations about the outcome of their actions (or failure to take action), their confidence that their actions will lead to the desired outcome (self-efficacy), and barriers to performance of the behaviour, which can be personal, situational or, in the case of health behaviours, may be rooted in the health care system.

Self-efficacy plays a pivotal role because whatever a person's motivation, unless they believe that they can achieve the desired outcome through their actions, they will have little incentive to perform a behaviour or persevere to overcome difficulties. Self-efficacy therefore influences the goals people set for themselves, the outcomes they expect to achieve through their efforts and the perseverance they will show in the face of obstacles (Bandura, 2000).

Bandura outlined four factors that influence self-efficacy and therefore can be targeted in order to increase self-efficacy and hence encourage behaviour change. One important way of increasing self-efficacy is through mastery. Success in performing a behaviour builds self-efficacy thereby increasing the likelihood that the behaviour will continue and more ambitious goals set. By contrast, failure undermines self-efficacy and discourages continued performance of the behaviour. Self-efficacy beliefs can also be strengthened through vicarious experience. This is gained through modelling the successful behaviour of a person with whom one identifies such as another patient living with the same illness. Social persuasion can also strengthen a person's sense of self-efficacy, for example an encouraging health professional could persuade patients that they have the capability to perform a given behaviour. Finally self-efficacy beliefs can be strengthened by reducing feelings of stress that can lead people to misinterpret their physical states and thus misjudge their capabilities.

### **3.3 Strategies to facilitate behaviour change**

These theoretical models provide a basis for understanding cognitions that influence self-management behaviour and therefore suggest possible targets for interventions that aim to change behaviour. A number of strategies have been identified that are considered important in facilitating behaviour change.

#### **3.3.1 Goal selection**

Selection of behavioural goals is a prerequisite of self-management. According to Creer & Holroyd (1997), goal selection can occur only after preparation, for which patients require both information about how their condition can be managed and the skills needed to do so. Creer & Holroyd view goal selection as a collaborative activity between patients and health professionals. Once goals are established it then

becomes the responsibility of the patient to utilise the self-management skills that have been taught in order to achieve those goals.

### **3.3.2 Implementation intentions**

Selecting a goal is an important step but ensuring that the goal is reached requires more than good intentions (Gollwitzer, 1999). Research on the Theory of Planned Behaviour, for example, has highlighted the gap between what people say they intend to do and actual performance of that behaviour (Armitage & Conner, 2001). Gollwitzer's Model of Action Phases differentiates between goal intentions and implementation intentions. While the former specify a desired end state, the latter specify how that state will be achieved. By breaking down when, where and how the given behaviour will be performed, the goal is more likely to be achieved (Sheeran, 2002).

### **3.3.3 Self-monitoring**

Creer & Holroyd (1997) have asserted that "self-monitoring provides the foundation for self-management". Systematic recording of information, about symptoms for example, can serve the purpose of increasing patients' awareness of what is happening in their illness and how it changes over time. It can also help patients to identify conditions that affect the outcome being monitored and continual feedback can serve to encourage the change process (Bandura, 1997). The self-monitoring process enables patients to identify whether they are reaching their goals and is considered an essential feature of self-regulatory processes (Karoly, 1993).

### **3.3.4 Stimulus-control**

Stimulus-control is a behavioural learning technique that involves establishing appropriate cues to stimulate performance of a new behaviour. By pairing a new behaviour with an already established, habitual behaviour, the new behaviour is more

likely to become established also. For example, one way of assisting people who repeatedly forget to take their medication would be to establish more effective cues to help them remember. Using daily routines or habits is useful so one approach could be to establish a link between taking medication and a routine such as brushing one's teeth or a regular mealtime. The association could be made by keeping medication, or a visual reminder such as a medication chart, in a prominent position by the related behavioural cue.

Conversely, removing cues to unwanted behaviours can help to reduce them. For example, a person trying to give up smoking is encouraged to remove smoking-related cues such as ashtrays and cigarette lighter and to break the links between behaviours that they usually pair with smoking such as avoiding places where they are tempted to smoke.

### **3.3.5 Problem-solving**

Training in problem-solving skills developed from a cognitive-behavioural approach in clinical psychology which recognised the importance of these skills in enabling people to adapt to the range of problems they may encounter through their lives (D'Zurilla & Nezu, 2001). This does not involve solving people's problems for them by advising them what to do, but entails helping people to think through their difficulties and decide on a solution that best suits them.

D'Zurilla & Goldfried (1971) set out five key components to the problem-solving process. These are:

- a. Problem Orientation - the way a problem is perceived by the individual is crucial for successful problem solving. Facilitation of a positive problem orientation is important so that the individual can see the problem as a challenge which can be



overcome in contrast to a negative problem orientation in which the problem is viewed in a pessimistic way that can inhibit problem-solving attempts

- b. Problem definition and formulation – this involves gaining a clear understanding of the nature of the problem and breaking it down into smaller, more manageable parts
- c. Generation of alternative solutions – by brainstorming several alternative possible ways of dealing with a problem, it should be possible to identify the strategy which is likely to be most effective
- d. Decision making – this involves weighing up the pros and cons of each alternative generated in the previous step and selecting the one which is considered the most appropriate
- e. Solution implementation and verification – the final step involves trying out the chosen strategy, evaluating its effectiveness and adapting the strategy or choosing a new strategy as appropriate

Although these steps have been presented sequentially, successful problem solving is likely to involve movement back and forth between the different stages before the process is complete.

### **3.3.6 Cognitive restructuring**

Patients' beliefs about themselves (e.g. I'm not the type of person who can change) or their illness (e.g. heart failure is an acute illness) may impede their self-management efforts therefore it is important to address mistaken or unhelpful beliefs. Cognitive restructuring, an element of cognitive-behavioural therapy, is a strategy that can be used to facilitate the development of more helpful beliefs by challenging aspects of patients' thinking. Common thinking biases have been identified (White, 2001), for example, a tendency to catastrophise, i.e. to think about events in the worst possible

terms, which may lead to patients not taking action to self-manage their illness if they think that whatever they do will make no difference. Patients can be encouraged to look for alternative ways of thinking that are more conducive to effective self-management.

### **3.3.7 Social support**

Self-management of a chronic illness does not occur in isolation from members of patients' family and social network accordingly support from these significant others is potentially an important influence on self-management behaviour (Gallant, 2003). In research, this support has been termed 'social support' and has been conceptualised both structurally, i.e. the size and composition of a person's social network, and functionally, i.e. how a person perceives and evaluates the adequacy of their support network. It is the latter which appears to be most closely related to health (McNally & Newman, 1999). Social support generally has a positive impact on health outcomes but the reverse can also occur (Gallant, 2003). A review by DiMatteo concluded that adherence to medical treatment is higher in those from cohesive families but lower in those from families that are in conflict (DiMatteo, 2004).

Involving partners or other members of a patient's network in an intervention may help to facilitate self-management by enhancing their understanding of the patient's illness and encouraging them to engage in supportive behaviours.

## **3.4 Factors influencing self-management in heart failure**

The theories outlined above describe some of the constructs that potentially play an important role in self-management. The research that has examined potential factors associated with self-management of heart failure will now be reviewed. This research was not necessarily conducted from a self-management perspective and typically focussed on patient 'compliance' or 'adherence' to medication or to the practice of 'self-

care' behaviours, but given that the behaviours addressed form part of heart failure self-management, the studies are included here. The way self-management was assessed was not consistent across studies, for example the review by van der Wal et al reported that assessment methods included interview, a number of different questionnaires, electronic monitoring and chart review, which is likely to influence the findings. It should be noted that the studies are mostly cross-sectional and examine associations with self-management. None were identified that attempted to change potentially modifiable variables in order to improve self-management.

### **3.4.1 Demographic factors**

Studies that sought to identify potential influences on self-management behaviour commonly examined demographic characteristics.

Studies that examined the relationship between age and self-management showed some consistency, with most studies finding that older age was associated with better self-management of at least some of the recommended behaviours. Although Rockwell & Riegel (2001) did not find any association between age and self-management, Chriss, Sheposh, Carlson et al (2004) reported better self-management among older patients, and Artinian et al., (2002), Monane, Bohn, Gurwitz et al., (1994) and Evangelista Berg & Dracup, (2001) all reported that older patients were more likely to follow their medication regimen. When Evangelista, Doering, Dracup et al (2003) compared older ( $\geq 65$  years) and younger ( $< 65$  years) patients, they found no difference in keeping medical appointments, taking medication, smoking cessation or alcohol abstinence but older patients were more likely to follow recommended dietary advice and take exercise.

Studies that examined the relationship between gender and self-management in heart failure showed inconsistent results (van der Wal et al., 2005). No gender differences were found by Rockwell & Riegel (2001), Evangelista, Kagawa-Singer, & Dracup (2001) or van der Wal, Jaarsma, Moser et al (2006). However, Chriss et al (2004) found that male gender was associated with better self-management whereas Monane et al (1994) found that females were more likely to keep to their digoxin regimen. The study by Artinian, Magnan, Sloan, & Lange, (2002) did not find any gender differences in overall self-management behaviour but men were more likely than women to report obtaining an annual flu vaccination.

Neither Evangelista, Berg, & Dracup (2001) nor Artinian et al (2002) found any relationship between ethnicity and overall self-management behaviour but on individual behaviours, the latter study found that African-American patients were more likely than whites to seek medical assistance in response to signs of deterioration whereas white patients were more likely to take their medication and get an annual flu vaccination.

The findings relating to education level and self-management are also inconsistent. Chriss et al (2004) did not find an association between education and self-management whereas in the study by Artinian et al (2002) higher education was associated with taking medication as prescribed and less use of convenience foods. Chui, Deer, Bennett et al (2003) also found that education predicted medication adherence. Although Rockwell & Riegel (2001) found that a higher education level was predictive of better self-management, it predicted only 4.6% of the variance. In one study, a lower education level was associated with better overall self-management behaviour although it seems to be related mainly to fluid restriction (van der Wal et al, 2006).

In the studies that used multivariate analysis, demographic factors accounted for only a small percentage of the variance in self-management. For example Rockwell & Riegel

(2001) found that gender, socioeconomic status, age, education, along with social support, co-morbidity and symptom severity explained only 10.3% of the variance in self-management. Similarly, Chriss et al, (2004) found that age, gender and education, along with comorbidity, social support satisfaction, activity and NYHA class, explained just 14.8% of the variance. A slightly higher percentage of variance was explained in the study by Evangelista, Berg & Dracup (2001). Age, race, marital status, and years of education, along with the variables of mental health, physical health, health satisfaction and neuroticism explained 24% of the variance in the overall self-management score.

The findings in self-management of heart failure appear to replicate those in the wider literature on adherence to medication which have not shown consistent relationships between adherence and demographic factors, with the possible exception of age (Horne, 1998). These studies serve to highlight that associations between demographic characteristics and self-management are not consistent across all heart failure self-management behaviours, reinforcing that people may be effective self-managers in some areas but not others.

### **3.4.2 Disease and treatment related factors**

The nature of the relationship between disease severity and the performance of self-management behaviour appears to vary according to which behaviour is being examined. For example, perhaps not surprisingly, Ni et al (1999) found that those in NYHA class III and IV i.e. those with more severe heart failure, did less exercise than those in classes I and II, however, higher NYHA has been associated with better adherence to medication (van der Wal et al, 2005). Rockwell & Riegel (2001) found that greater symptom severity was associated with better self-management although it explained only 2.7% of the variance. In contrast, Evangelista, Berg & Dracup (2001) found that self-management was better in those reporting better physical health and

greater health satisfaction. Artinian et al (2002) found that patients who reported more shortness of breath were less likely to weigh themselves but Chriss et al (2004) did not find any relationship between NYHA or ability to perform activities of daily living and self-management.

Many patients with heart failure have co-morbid conditions and it is possible that these could limit their ability to self-manage effectively. For example some patients have reported being unable to weigh themselves because of restricted eyesight or not being able to stand on the scales independently and not exercising because of disability (Jaarsma et al, 2000). Chriss et al (2004) found that co-morbidity was an independent predictor of self-management behaviour three months later.

Complexity of the medication regime may be another important factor in how effectively people self-manage (Evangelista et al., 2003). Bohachick, Burke, Sereika et al (2002) compared rates of adherence to ACE inhibitors between those whose prescriptions were for once, twice or three to four times a day and found rates of 90%, 84% and 68% respectively. More complex regimens may be more difficult to remember and implement correctly. However the number of different medications may not necessarily be an issue; Monane et al. (1994) found that people taking a greater number of different medications were more likely to follow their digoxin regimen.

The duration for which patients have been living with heart failure may influence how effectively they self-manage. Carlson, Riegel & Moser (2001) found that experienced patients who had a sudden weight gain were more likely than the newly diagnosed to take responsive action by limiting their salt intake and using additional diuretics. Riegel et al divided patients into those who had been diagnosed with heart failure for less than 2 months and those with a longer-standing diagnosis and found that patients who had

been diagnosed for longer than two months reported better self-management behaviour (Riegel, Carlson, Moser et al, 2004).

### **3.4.3 Knowledge**

In common with findings in other chronic illnesses (Coates & Boore, 1996; Taal, Rasker & Weigman, 1997; Gibson, Coughlan, Wilson et al, 2000) there is not a strong relationship between knowledge and self-management in patients with heart failure. The only study that reported a positive relationship between them was by Van der Wal et al (2006) who found that a higher knowledge score was associated with fluid restriction and weighing behaviour. Other studies did not confirm this finding, for example, Michalsen et al found that 55.3% of patients had at least basic knowledge about their prescribed drug treatment however knowledge was not significantly correlated with patients' adherence to recommended medication (Michalsen, Konig & Thimme, 1998). Of 42 non-adherent patients, 47.6% lacked basic knowledge about at least one prescribed drug and among 137 adherent patients, 43.8% lacked basic knowledge about at least one prescribed drug i.e. levels of knowledge were similar among adherent and non-adherent patients.

Ni et al (1999) also found that knowledge was not sufficient to predict self-management behaviour. Although scores were correlated, knowledge did not remain a significant predictor of self-management in multivariate analysis. Only 58% of those patients who considered daily weight monitoring to be important weighed themselves daily and 14% weighed themselves once a month or less. Of those who considered restricting sodium intake to be important, only 38-40% reported always avoiding salty foods. When De Geest, Scheurweghs, Reynders et al (2003) compared patients with heart failure admitted to cardiology and geriatric wards, they found that knowledge of treatment recommendations was higher in the former but adherence to some aspects of the

regimen was higher in the latter, again suggesting that knowledge alone does not explain self-management behaviour.

### **3.4.4 Psychological factors**

#### **3.4.4.1 Self-efficacy**

Very little research has been conducted into the role of cognitions in heart failure self-management. One early study was identified that examined the relationship between self-efficacy and self-management, both of which found a positive relationship. Ni et al (1999) found that lower self-efficacy was associated with poorer adherence to recommended self-management behaviours. A more recent study (Schweitzer, Head, & Dwyer, 2007) also found that self-efficacy was a significant predictor of performance of self-management behaviours.

It is important however that self-efficacy is not misplaced. Carlson, Riegel & Moser (2001) found that patients were confident about their ability to evaluate symptom importance despite the fact that misperceptions about the importance of specific symptoms were common.

#### **3.4.4.2 The role of illness and treatment beliefs in heart failure self-management**

Research into cognitive factors in self-management of heart failure is at a very early stage with little currently known about the beliefs patients hold about their illness or their ability to manage it.

Horowitz, Rein & Leventhal (2004) highlighted that heart failure programmes conducted to date have not had the benefit of information about which potentially modifiable factors are involved in inadequate self-management. They were interested in patients'



knowledge and beliefs about heart failure because, according to the self-regulation model (Leventhal et al., 1984) which guided their research, the way patients self-manage is a reflection of how they conceptualise their experience of the disease.

In a qualitative study of 19 patients, Horowitz Rein & Leventhal (2004) found that patients' representations of their heart failure lacked depth and breadth in that they did not make the connection between the disease and their chronic symptoms and were unable to give an explanation of what caused their heart failure or its symptoms. These beliefs had implications for patients' self-management because they did not recognise that they could minimise fluid build-up and detect signs of deterioration through self-management practices. For example, some patients who held an acute model of their heart failure thought they needed to take diuretics only when their symptoms became severe. This may help to clarify why it is often insufficient to provide patients with information about what they need to do to manage their illness e.g. take diuretics, without gaining an understanding of the model they hold of their illness which may influence how they put the information into practise. Horowitz et al found that lack of a coherent representation of the connection between the disease and its symptoms meant that signs of deterioration such as weight gain, breathlessness or oedema were not necessarily followed by an appropriate response. Few patients self-monitored for signs of deterioration, by regular weighing for example, but took action only once their symptoms had become severe enough to require emergency medical care. Horowitz et al concluded that patients mostly held a model of heart failure as an acute condition with episodic exacerbations rather than a chronic condition requiring continuous monitoring and self-management.

Just one other study was identified that examined the role of beliefs about the treatment regimen in heart failure. When van der Wal et al (2006) examined the

relationship between patients' beliefs about their recommended medication and dietary regime, they found that patients who perceived benefits from their diet and medication were more likely to perform recommended health behaviours.

#### **3.4.4.3 Mood**

Depression is recognised as a risk factor for non-adherence to medical treatment. A review by DiMatteo, Lepper & Croghan (2000) for example, found that the odds of not following medical treatment recommendations were 3 times greater in depressed than in non-depressed patients. Only two studies were identified that examined the relationship between mood and self-management in heart failure and, not surprisingly, found that lower mood is associated with poorer self-management. Van der Wal et al (2006) found that patients reporting more depressive symptoms were less likely to exercise and Evangelista et al, (2001) found that better mental health and lower neuroticism were predictive of better self-management.

#### **3.4.4.4 Lack of social support**

The relationship between social support and self-management of heart failure is unclear with studies reporting inconsistent findings. Happ, Naylor & Roe-Prior (1997) et al found that absence of strong social support was related to poorer adherence and patients interviewed by Simpson, Farris, Johnson & Tsuyuki (2000) considered support from family and friends to have a positive impact on adherence. Ni et al (1999) found poorer self-management among patients who were unmarried. However, Rockwell & Riegel (2001), Evangelista et al (2001) and Chriss et al (2004) did not find a relationship between social support and self-management behaviour. A study by Artinian et al (2002) suggested that social support may have a positive influence on some behaviours but a negative impact on others. They found that patients who lived with others were more likely to seek medical assistance when symptoms worsened and

less likely to eat convenience foods than those who lived alone. They were, however, less likely to be physically active than those who lived alone.

### **3.4.5 Summary**

These findings indicate that a fairly limited amount of work has investigated factors that may influence self-management in heart failure. This is a fairly new area of investigation with almost all of the studies having been published during the current decade. Most have examined a narrow range of potential influences, concentrating mainly on demographic characteristics. The findings are also confounded by the use of different measures of self-management/adherence and a focus on different behaviours. Furthermore studies have not systematically assessed the relationship between potential influences on self-management, the performance of self-management behaviours and health outcomes. Most of the studies were cross-sectional so there is also a need for longitudinal studies to examine how these factors influence each other over time. It is clear that very few studies in heart failure have drawn on the extensive literature that exists on self-management of chronic illness.

## **3.5 A SYSTEMATIC REVIEW OF INTERVENTIONS TO IMPROVE PATIENT SELF-MANAGEMENT OF HEART FAILURE.**

### **3.5.1 Introduction**

This next section reports the findings of a systematic review of interventions developed to improve care for patients with heart failure to examine how they have addressed the issue of patient self-management. The review is limited to papers published to February 2001, in order to provide an overview of the field at the time when work on the current study commenced and on which the current intervention was informed.

While it has been recognised that people with heart failure have an important role to play in managing their illness and that self-management is often sub-optimal, it is not clear whether interventions that have tried to improve outcomes for patients with heart failure have concentrated solely on improving medical aspects of treatment i.e. disease management, or have also included methods aimed at enhancing patient self-management.

When this study commenced, interventions designed to improve heart failure management had been reviewed in three papers, (Philbin, 1999; Rich, 1999; McAlister et al., 2001). The reviews identified only a small number of studies, the largest being 16 studies in Rich, of which only 6 were randomised trials. This appears to reflect the relatively undeveloped status of the field at that time. The later review, by McAlister et al, identified 11 randomised trials. Although most of the interventions included patient education, the reviews gave only a brief summary of the interventions and did not report or examine the content of the education component in any detail. The extent to which studies aimed to enhance the role of the patient in managing their heart failure

was not reviewed nor did the reviews examine whether any changes in self-management resulted in changes in health outcomes. A more detailed examination of the way studies addressed these issues was therefore required to inform the intervention planned in this study.

### **3.5.2 Aims**

The aims of this systematic review were to examine the effectiveness of interventions in heart failure and the extent to which they promoted self-management. In particular, it examined which self-management components the interventions addressed, what strategies they adopted in order to encourage behaviour change and how effective they were in promoting self-management. It also examined whether changes in self-management resulted in changes in health outcomes.

### **3.5.3 Methods**

#### **3.5.3.1 Search**

Electronic database searches of Medline 1966-February 2001, Embase 1980-February 2001 and PsycInfo 1972-February 2001 were conducted. Search terms used were (heart failure or cardiac failure or cardiomyopathy) and (patient education or self-management or non-pharmacological or adherence or behavior\* or health promotion or nurse or multi-disciplinary) and (program\* or intervention or therapy). Studies were included if i) they reported a prospective evaluation of an intervention to improve heart failure management which included an educational and/or self-management component i.e. they aimed to improve the patients' self-management of their heart failure, not only the medical management ii) the study population included adults ( $\geq 18$  years) with heart failure, iii) they were published in English, iv) the design was either pre-test - post-test or a controlled trial, v) effects were tested statistically.

The titles of all papers identified in the search were screened. Where the study appeared to evaluate an intervention, the abstracts were obtained and reviewed. Full articles were examined for studies that met the inclusion criteria.

### **3.5.4 Results**

The search identified 21 studies published between 1992 and 2000 (Table 3.1). The majority (n=14) were conducted in the USA. Only one of the studies was conducted in the UK (Varma, McElnay, Hughes et al, 1999). In comparing the studies included in this systematic review with earlier reviews, there was overlap in the studies included, with ten of the sixteen studies included in the review by Rich, five of the seven in the review by Philbin and nine of the eleven in the review by McAlister et al. Exclusion of some of the studies that had been included in earlier reviews usually occurred because they did not include an education component or were not prospective evaluations of interventions.

#### **3.5.4.1 Study design**

Fifteen of the studies (71%) were controlled trials, the remainder were single group pre-post studies.

Only one study (Gattis, Hasselblad, Whellan & O'Connor, 1999) reported that cardiologists involved in the treatment of study patients were blind to study group allocation.

### **3.5.4.2 Sample demographics**

Study samples ranged in size from 20 to 504. Several of the studies were small with ten studies having fewer than 100 participants. Mean age ranged from 52, in a sample of patients referred for transplant, to 80 in a study with an inclusion criterion of age  $\geq 65$ . Sex distribution ranged from 33% to 98% male. Given the age and sex distribution of the general heart failure population, a number of the studies would appear to comprise samples that are not representative of the patient population. Most studies did not report socioeconomic data.

### **3.5.4.3 Disease Variables**

#### **3.5.4.3.1 *Inclusion and exclusion criteria***

Most studies (16/21, 76%) recruited from patient populations who had been admitted to hospital with a diagnosis of heart failure i.e. those at a high risk of readmission and death. Studies typically excluded those who had cognitive impairment, psychiatric illness, were living in residential care or outside the hospital catchment area, did not speak the language of the country where the study was conducted, had a terminal illness or were awaiting cardiac surgery. Recruitment rates, including the numbers who were excluded and those who refused, were often not reported, making it difficult to draw conclusions about the representativeness of the interventions in relation to the general population with heart failure. In the first large randomised controlled trial (Rich et al., 1995) for example, only 21.6% of patients who fulfilled the criteria for diagnosis of congestive heart failure were randomised into the study.

#### **3.5.4.3.2 *Diagnosis of Heart Failure***

Several studies did not specify the criteria on which the diagnosis of heart failure was based nor if the study was limited to those with left ventricular systolic dysfunction.

Diagnostic criteria that were reported did not always include objective confirmation of heart failure, for example by echocardiography.

#### *3.5.4.3.3 Disease severity*

Disease severity was reported differently across studies, making comparison difficult. Extent of left ventricular systolic dysfunction as evidenced by left ventricular ejection fraction (LVEF) was reported in seven studies and the mean ranged from 21% to 44%.

Eight studies reported severity of functional impairment by New York Heart Association (NYHA) classification but failure of most studies to report the time of the assessment limits the usefulness of this information. It would be expected that most patients would be in class III or IV at the time of an admission to hospital but class I or II by the time they are well enough to be discharged. To compare severity of functional impairment across study populations, uniformity in time of NYHA assessment would be required.

#### *3.5.4.3.4 Co-morbidity*

In the population of patients with heart failure, who are mostly elderly, presence of co-morbid illness is common (Krum & Gilbert, 2003) and this is likely to contribute to the probability of readmission to hospital (Braunstein, Anderson, Gerstenblith et al, 2003) as well as increasing self-management demands. Eight studies did not report the prevalence of co-morbid illnesses and others varied in the number of illnesses they reported on. Of the 13 studies that reported co-morbidity, eight studies reported rates of hypertension, which ranged from 29% (Jaarsma et al., 1999) to 76% (Rich et al., 1995). In the 6 studies that reported atrial fibrillation (AF) rates ranged from 18% (Fonarow, Stevenson, Walden et al, 1997) to 41% (Ekman, Andersson, Ehnfors et al, 1998). All the studies reported rates of diabetes, which ranged from 15% (Shah, Der,



Ruggerio, Heidenreich, & Masssie, 1998) to 34% (Stewart, Marley, & Horowitz, 1999). Rates of lung disease in 6 studies which reported it ranged from 20% (Smith, Fabbri, Pai, Ferry, & Heywood, 1997) to 36% (Stewart, Pearson, & Horowitz, 1998; Stewart, Marley & Horowitz, 1999). A number of other illnesses, for example arthritis, are likely to have been common in this population but were not reported. The impact of co-morbid illnesses on study outcomes was not examined specifically in any of the studies but comorbid illnesses are likely to have played a role in the number of hospital admissions for reasons other than heart failure.

#### **3.5.4.4 Standard care**

The nature of standard medical care that patients received, aside from the intervention under study, is an important consideration. If standard care is suboptimal, an intervention has the potential to make a greater impact. For example, if patients in the intervention group, but not the standard care control group, receive treatment according to recommended guidelines it would not be surprising if outcomes are better in the intervention group. Factors that have been identified as contributing to early readmission to hospital include discharge when not yet clinically stable and under-prescription of recommended heart failure medication. It is important therefore to consider whether interventions simply optimise medical care in the intervention arm of the study but not the controls. Differences in standard care in different health care settings means that the optimised intervention arm in one study may be receiving care comparable to the control group in a study conducted in another health care setting with better standard care.

In the studies under review, standard care was not always described and varied considerably in those studies where it was reported. For example, in a Swedish study (Ekman et al, 1998) follow-up post discharge was generally by GP. In contrast, in an

Australian study (Stewart et al, 1999), standard care included in-patient and community-based contact with a cardiac rehabilitation nurse, dietician, social worker, pharmacist and community nurse where appropriate plus an appointment with the primary-care physician, the cardiology outpatient clinic, or both, within 2 weeks of discharge and regular outpatient review by the cardiologist throughout the follow-up period.

None of the studies reported on whether medical care was optimised for all study patients but one indicator is the proportion of patients who had been prescribed recommended heart failure medication. Thirteen studies reported details of medication prescribed at baseline however the measurement time was not always clearly specified. In those studies that reported medication at discharge from hospital, the proportion of patients who were prescribed ACE inhibitors ranged from 53% (Riegel et al, 2000) to 81% (Stewart et al 1998) and diuretic prescription ranged from 84% (Rich et al, 1995) to 99% (Stewart et al, 1998), indicating heterogeneity in the delivery of recommended medical treatment between studies.

Differential prescription rates between study groups would suggest that at least part of any intervention effects could be attributable to optimisation of medical treatment rather than other components of the intervention. Only two studies (Cline, Israelsson, Willenheimer, Broms, & Erhardt, 1998; Gattis, Hasselblad, Whellan, & O'Connor, 1999) reported differences in medication prescription between intervention and control groups, both of which were found at follow-up. As other studies did not report medication prescription at follow-up, it is not known to what extent optimisation of treatment differed between intervention and control groups.

The amount and content of any education provided as part of standard care was not always reported, making it difficult to tell whether control groups were provided with even basic information about their treatment and how to manage their illness. In the eight studies that did report details, standard care information provision varied. For example, Schneider, Hornberger, Booker, Davis, & Kralicek, (1993) reported that usual education provided to the control group by the staff nurses was thought to vary between patients and to be haphazard at times. In contrast, Linne, Liedholm, & Israelsson (1999) compared two education programmes in which the control condition received standardised general information about heart failure and its management along with instruction on weight monitoring and individual limits for short-term weight change. This may have been equivalent to the information given to intervention groups in other studies.

#### **3.5.4.5 Interventions**

Most of the interventions aimed to improve delivery of medical care through a combination of one or more of medication review, enhanced discharge planning and enhanced follow-up (Table 3.2). Interventions were included in this systematic review only if they incorporated an education or self-management component, however the sections that follow will show that most of the included studies adopted a traditional information giving model rather than what would usually be considered self-management. For this reason, they are referred to as 'patient education' rather than 'self-management'.

##### **3.5.4.5.1 *Improving delivery of medical care***

Almost all of the studies incorporated a component that aimed to improve patients' medication regimen. For example, several included medication review and simplification, which in one study (Schneider, Hornberger, Booker et al., 1993) included

adaptation of the medication schedule to fit in with the patient's everyday routine. Four interventions included input from a pharmacist.

Five interventions included enhanced discharge planning. This incorporated, for example, identification of anticipated problems with the treatment regimen, physical functioning or home environment, putting the appropriate services in place and ensuring that there was adequate communication between hospital and primary care services. The variability in standard care highlighted above must be taken into account when considering the impact of such intervention components.

Thirteen interventions (62%) included enhanced follow-up by a health care professional. This involved home visits, clinic out-patient visits and telephone calls, but studies varied considerably in the combination used and in the number of contacts, as well as the period over which the intervention was delivered. Interventions ranged from a single home visit (Stewart et al., 1998) to three home visits within a week of discharge then at regular intervals plus telephone follow-up (Rich et al., 1995) to easy access to a nurse-led clinic as required (Cline et al., 1998).

#### *3.5.4.5.2 Patient Education - Self-Management behaviours targeted*

Patient education typically included information about heart failure and its treatment, including information about medication and instruction in what patients need to do to manage their illness. Study reports did not always provide detailed descriptions of the education components so some self-management behaviours may have been omitted. Sixteen different self-management behaviours were identified from the papers (Table 3.3). All studies addressed at least one self-management behaviour but there was considerable variation between studies. The most commonly addressed behaviours

were medication adherence (n = 17, 81%) and self-monitoring through daily weighing and symptom monitoring (n = 16, 76%). Nine studies (43%) addressed sodium restriction and a further 4 studies (19%) incorporated dietary advice which, although it was not mentioned specifically, may have included sodium restriction. Exercise is increasingly recognised as an important part of heart failure self-management but only 5 (24%) of the interventions published up to February 2001 included exercise.

#### *3.5.4.5.3 Patient education – emotional aspects of self-management targeted*

Four (19%) studies addressed emotional aspects of heart failure self-management. A study in which only 7 patients were in the therapy arm evaluated an intervention that included cognitive therapy, exercise training and a dietary intervention (Kostis, Rosen, Cosgrove, Shindler, & Wilson, 1994) and Luskin et al (Luskin, Newell, & Haskel, 1999) carried out a pilot study of stress management training. A multidisciplinary disease management programme included an out-patient support group (Riegel, Carlson, Glaser, & Hoagland, 2000) and a mail-delivered programme included components dealing with depression and stress (Serxner, Miyaji, & Jeffords, 1998). A fifth study (Jaarsma et al., 1999) referred to the provision of support for psychosocial problems but it is unclear if this comprised any more than discussion of problems with a nurse.

#### *3.5.4.5.4 Behaviour Change – Theoretical Framework*

All the interventions included in this systematic review incorporated components that addressed aspects of self-management. Apart from the cognitive therapy and stress management interventions referred to above, most did not make reference to any theoretical basis to their interventions. Exceptions were two studies (Jaarsma et al, 1999; Schneider et al, 1993) that designed interventions based on Orem's nursing theory of self-care (Orem, 1995). This describes three sets of limitations to self-care –

limitations of knowledge, decision making and skills. Another study (West, Miller, Parker et al, 1997) referred to social learning theory but did not describe how it informed the intervention content. Riegel et al (2000) implemented a multidisciplinary programme, describing the team philosophy as self-care, which was conceptualised as involving four different stages but it is not clear how these were identified or if they were theoretically based. Serxner Miyaji & Jeffords (1998) asserted the importance of patients' self-efficacy in managing their illness and also measured it but they did not report how they addressed self-efficacy in their intervention.

The implicit model underlying most of the studies would appear to have been that informing patients of the recommended self-management behaviours would be sufficient to bring about behaviour change. Some studies that did appear to recognise that the issue is more complex did not necessarily make use of the literature on health behaviour change.

#### *3.5.4.5.5 Behaviour change techniques used*

Most of the interventions included in this systematic review did not utilise established behaviour change techniques. Only five (24%) studies made any reference to what strategies were used to promote behaviour change, reinforcing the implication that most relied on information being sufficient. Studies that did make at least some reference to behavioural strategies were nevertheless often unclear, and did not refer to a recognised theory but rather used vague terms such as 'behavioural interventions' (West et al., 1997) and 'remedial counselling' (Stewart et al, 1998; Stewart et al., 1999) without providing any detail of what these entailed. Although Bushnell (1992) did not report a theoretical framework, the intervention did initiate patient performance of self-management behaviours in hospital which, by encouraging performance mastery,

could potentially increase patients' self-efficacy to maintain the behaviours post discharge. In another study (Ekman et al., 1998) behavioural goals were set, for example weighing three times a week, but it is not clear if these were chosen by the nurse or the patient. In the intervention reported by Schneider et al (1993) the nurse posed problems and discussed possible actions and probable results with the patient. Several of the interventions included medication and weight charts which may have acted as aide memoirs to encourage adherence.

#### *3.5.4.5.6 Mode of delivery*

One intervention was wholly mail-delivered (Serxner et al 1998). Eleven interventions (52%) were delivered by a nurse specialist (Bushnell, 1992; Schneider et al, 1993; Weinberger et al, 1996; Fonorow et al, 1997; Smith et al, 1997; West et al, 1997; Cline et al, 1998, Ekman et al, 1998; Shah et al, 1998; Jaarsma et al, 1999; Stewart et al, 1999) and two by a pharmacist (Gattis et al, 1999; Varma et al, 1999) while two were delivered by both a nurse and pharmacist (Stewart et al, 1998, Linne et al, 1999). Of the other studies, only the interventions by Kostis et al (1994) and Luskin et al (1999) did not include a nurse in the team. Four interventions were delivered by a multi-disciplinary team (Rich et al, 1993; Kostis et al, 1994, Rich et al 1995; Riegel et al, 2000). The small number of studies that made reference to behaviour change techniques did not report any form of training in behaviour change techniques for the staff delivering the intervention. These skills do not form part of usual training for most health professionals.

The place of delivery of the interventions included one or more of in hospital, home visits, out-patient clinics and by telephone. Almost all studies that recruited patients during a hospital admission commenced the intervention during the hospital stay. Other

sessions took place either at home visits or clinic appointments but not both, and telephone contact was used to follow up and supplement these sessions.

#### *3.5.4.5.7 Intervention intensity*

The interventions varied considerably in intensity, from a single 20 minute session (Schneider et al, 1993) to approximately 7 home visits over a 6-month period (Riegel et al, 2000), while Cline et al (1998) offered access to a nurse clinic for the duration of the 12-month study period.

In studies that combined patient education with other components, the intensity of patient education was difficult to assess as studies often did not provide detailed information. Some studies, such as Rich et al (1995), reported that education was reinforced at each meeting but others did not make this explicit.

#### **3.5.4.6 Study duration**

The duration of follow-up also varied between studies. Luskin et al (1999) assessed study outcomes one week post intervention, however this was unusual. Studies mostly assessed outcomes at 3, 6 or 12 months after baseline. It is important that in some studies the assessment will have been conducted several months after the intervention finished whereas in others the intervention may have been continuing throughout the follow-up period. For example, Varma et al (1999) assessed outcomes 12 months after a brief intervention whereas in the study by Cline et al (1998), which also reported 12 month outcomes, clinic access was available to the intervention group throughout this period.



### **3.5.4.7 Outcomes**

The most frequently measured outcomes in the studies included in this systematic review were reduction in unplanned admissions to hospital and mortality. Although these outcomes are shown in the tables for both pre-post studies and controlled trials, the findings of studies with pre-post designs are less informative as they can not provide a clear indication of how much the intervention improves upon standard care. Some studies, such as West et al (1997), compared hospitalisations during the study period to an equivalent duration before the study began, however factors other than the intervention under examination, for example differences in the populations, could have influenced the findings.

#### **3.5.4.7.1 *Hospital Admissions***

Hospital admissions were reported in two ways in the studies reviewed. Some reported all cause hospitalisation and others reported hospitalisation for heart failure. Some studies reported both.

Sixteen studies reported hospitalisations for any cause of which 11 were controlled trials. Of the controlled trials, 4 reported significantly fewer hospitalisations in the intervention group than in controls. Only one study (Weinberger, Oddone & Henderson, 1996) reported significantly more hospitalisations in the intervention group. This study also included patients with diabetes and COPD and reported the significance level only for the whole sample, however the number of readmissions, days of rehospitalisation and proportion of patients readmitted for heart failure were all higher in the intervention than in the control group. The poorer outcomes in this study may have arisen because it was a generic intervention that provided increased access to primary care in contrast to others that were heart failure specific, often involving specialist follow-up.

Admissions for heart failure were reported in 10 studies of which 7 were controlled trials and one further study (Jaarsma et al, 1999) reported cardiac hospitalisations. Five studies reported statistically fewer admissions for heart failure in the intervention group than in the control group and no study reported more admissions in the intervention group.

Of the 9 controlled trials which compared length of hospital stay between intervention and control groups, Rich et al (1995), Stewart et al (1998) and Stewart et al (1999) reported significantly fewer total days spent in hospital in the intervention group. Only 2 studies reported duration of hospital stay for cardiac or heart failure admissions, neither of which found a significant difference between intervention and control groups. No study reported an intervention group spending significantly longer in hospital than controls.

#### *3.5.4.7.2 Mortality*

Sixteen studies reported mortality rates. Three month mortality reported by Rich et al, (1995) was 11% for the total sample and, although slightly higher in the controls than the intervention group, was not a statistically significant difference. Six-month mortality was reported in 9 studies and ranged from 4% (Gattis et al., 1999) to 34% in a small early study (Bushnell, 1992). Twelve-month mortality was reported in 2 studies in which it varied from 17% (Varma, McElnay, Hughes, Passmore, & Varma, 1999b) to 29% (Cline et al., 1998). No study reported a statistically significant difference in mortality between the intervention and control groups but there were usually more deaths in the control groups, except in the case of Jaarsma et al (1999) in which 26% of the intervention group and 17% of controls died within 9 months of discharge from hospital.

#### 3.5.4.7.3 *Admission-free survival*

Analysing the outcomes of hospital admissions and mortality separately is problematic because inevitably, longer survival allows for the possibility of more hospital admissions. The combined outcome of admission-free survival is therefore more accurate in assessing the impact of an intervention. Just 6 studies reported the numbers of patients who survived the study period without being readmitted to hospital. Of these, Rich et al (1995) and Stewart et al (1998,1999) reported statistically significant differences between the groups with more intervention group patients surviving without readmission.

#### 3.5.4.7.4 *Comparison of hospitalisation and mortality across studies*

An important factor to consider when comparing the efficacy of interventions across studies is not only whether a study reported better outcomes in the intervention group than in the control group, but also how the studies compared with each other on occurrence of events such as death or readmission to hospital. It is possible that an intervention performed well in comparison to its control group but not in comparison to interventions in other studies with non-significant outcomes. For example, Stewart et al (1999), reported significantly lower 6-month mortality in the intervention group (18%) than the control group (28%). In contrast, the study by Riegel et al (2000) did not report a significant effect of the intervention on mortality, however the overall 6-month mortality rate for the study was 9.2% i.e. approximately half the rate of the intervention group in Stewart et al (1999). Stewart et al also reported a significant difference in the number of hospital admissions between the intervention group (0.68 per patient) and the control group (1.18 per patient) in the 6-month follow-up period. Although Riegel et al did not find a significant difference between the intervention (0.63 admissions per patient) and control groups (0.60 per patient), outcomes for both were comparable to those of the intervention group in Stewart et al's study. Such findings could possibly

arise from differences in the quality of standard care between studies or differences in the study populations. The study by Stewart et al had a higher percentage of male patients and all patients had at least one previous admission to hospital however it is not possible to assess whether this explains the difference in outcomes. The standard care received by the control groups appears from the study reports to have been more structured and possibly more specialised in the study by Stewart et al so it is perhaps surprising that the control group in this study had poorer outcomes. The two studies reported NYHA at different timepoints so it is not possible to tell if one patient sample was more ill than the other at entry into the studies or whether this could explain the finding. Comparison across other studies included in this review was not possible because of the variability in the outcomes reported and duration of the follow-up period.

#### *3.5.4.7.5 Psychological well-being and Quality of Life*

Factors such as depression and anxiety could have an impact on other health outcomes and also affect patients' ability to manage their heart failure but few studies assessed the impact of their interventions on patients' psychological well-being. Depression and anxiety were assessed by Kostis et al (1994) who compared an intervention that incorporated exercise training, dietary intervention, cognitive therapy and stress management with a group receiving digoxin and a placebo control. This study reported significant improvement in anxiety and depression in the therapy group and deterioration in the other groups over the 12-week study period but the study was so small (a total sample size of 20 randomised to one of three groups) that the value of these findings is limited. In another small pre-post study (n = 14) evaluating a stress management programme, Luskin et al (1999) reported a significant improvement in perceived stress but not depression, anxiety, self-esteem or quality of life.

It is possible that an intervention which asks patients to increase self-monitoring of their illness and to make lifestyle changes could have the unintended effect of impairing their

quality of life. It is important therefore to look not just at clinical outcomes but also at the impact from the patient's perspective. Eight studies evaluated quality of life. Rich et al (1995) gave the Chronic Heart Failure Questionnaire (Guyatt, Nogradi, Halcrow et al., 1989) to a subset of 126 patients. Over the 90-day study period, quality of life improved in both groups but there was significantly more improvement in the intervention group ( $p=.001$ ) and they showed consistent improvement in all four subscales of the measure – dyspnoea, fatigue, emotional function and environmental mastery. Both West et al (1997) and Stewart et al (1999) found significant improvement in the physical composite scores of the SF-36 (Ware & Sherbourne, 1992), and although scores on the mental composite scores also improved, these were not statistically significant. In the latter study, effects on the physical component were not maintained at the 6 month follow-up. Smith et al (1997) found that quality of life measured with the Minnesota Living with Health Failure questionnaire (MLHF) (Rector, Kubo & Cohn, 1987) improved over the 6 month intervention period. Also using the MLHF, Stewart et al (1999) found that the intervention group reported better quality of life than controls at 3-month but not 6-month follow-up and Varma et al 1999 reported better scores in the intervention group at the 9-month but not 3, 6 or 12-month follow-ups. Cline et al (1998) did not find any difference between intervention and control patients in quality of life at baseline or at 12-month follow-up.

These studies indicate that the interventions did not have a detrimental impact on quality of life and in most cases had a beneficial effect, although the benefits appear to be short-lived.

#### 3.5.4.7.6 *Self-Management Behaviours*

Only five studies (24%) measured and/or reported practice of self-management behaviours as part of their intervention evaluation.

Three studies reported adherence to medication but different methods of assessment were used and the results were variable. Rich et al (1995), using a pill count 30 days post discharge, found a significantly higher rate of adherence to medication in the intervention group (82.5%) than in controls (64.9%). Varma et al (1999) also assessed medication adherence. Self-reported adherence did not differ significantly between intervention and control group patients at any assessment during the 12 month follow-up. Drug records from community pharmacists were available for a sub-sample of 23 patients of which more intervention group patients were adherent with all medications ( $p=.039$ ). Serxner et al (1998) found that patients who received a mail-delivered education programme were less likely than controls to report forgetting medication. Forgetting did not decrease in the intervention group post-intervention, but it increased in the controls.

Dietary behaviour was reported by two studies. Serxner et al (1998) found that patients in the intervention group were more likely than controls to report making positive dietary changes. A small study by West et al (1997) using a single group pre-post design reported a 38% reduction in sodium intake over the 6-month study period.

Jaarsma et al (1999; 2000) was the only study in which self-management behaviour was measured in any detail. This study assessed self-management behaviour on a 19-item scale and found that at baseline, patients in both groups practiced an average of 9 behaviours on the scale. They were most likely to report adhering to medicine (88%).

Fewer weighed daily (57%), restricted sodium (50%), contacted their doctor about leg oedema (42%) or breathlessness (45%), took exercise (54%) or noticed diuresis (22%). Both groups practiced a higher number at 1-month follow-up although this was greater in the intervention group. Practice decreased over time but was still significantly better in the intervention group at 3-month follow-up but not by 9-months. The increase over time was still significant in the intervention group, but not the control group at 9-month follow-up. Unfortunately Jaarsma et al (2000) did not report change for each behaviour so it is not possible to tell if the intervention was more successful in changing some behaviours than others.

So few studies examined performance of and changes in self-management behaviours that it is not possible to compare across studies or draw any conclusions about which type of intervention may produce the greatest enhancement in practice of self-management behaviours. It is encouraging nevertheless that the few studies which measured behaviours reported positive findings.

#### *3.5.4.7.7 The relationship between intervention composition and outcomes*

The heterogeneity in the effectiveness of the interventions in this systematic review makes it important to examine what components of the interventions or aspects of their delivery may have contributed to their effectiveness. It is of course possible that a component or group of components may influence some outcomes but not others.

All interventions included an education component but these were usually not described in detail therefore it is not possible to assess whether one type of education programme was more successful than others. Furthermore, as few studies evaluated behaviour, it is difficult to assess what role education may have played in changing behaviour and what impact any behaviour change may have had on study outcomes.

Of the 5 studies that assessed self-management behaviours, only two examined the relationship between these behaviours and other outcomes. Rich et al (1995) found that medication adherence was not predictive of readmission in univariate or multivariate analysis but there was a trend towards fewer multiple admissions in patients with  $\geq 90\%$  adherence. Jaarsma et al found that heart failure self-management behaviour correlated slightly with psychosocial adjustment at 3 and 9 months after discharge and with overall wellbeing score at 9 months. Self-care behaviour showed only a limited relationship with hospital readmissions. In the control group, self-care behaviour at 1 month after discharge was related to the number of readmission days for cardiac reasons at 3 months in that higher self-care behaviour scores were related to fewer readmission days. There were no significant relationships between behaviour and admissions at other time-points. Jaarsma et al (1999) also assessed self care agency - patients' self-ratings of their ability to care for themselves - and found that it was related to functional capabilities, symptoms and psychosocial adjustment to illness at 3 and 9 months and with overall score of wellbeing at 9 months. Three months after discharge, higher self-care agency scores in the intervention group was related to fewer GP contacts and fewer readmission days in the following 6 months. This relationship was not found in the control group.

It is possible that another component of the interventions was key, for example discharge planning or medication review, however examination of the studies did not reveal a clear pattern. The place of delivery of the intervention i.e. home visit, clinic visit, by mail and by telephone was another factor which varied between studies but again no clear pattern emerged of greater effectiveness for a single approach.

Intervention intensity did not appear to explain differences between studies. For example, in the study by Stewart et al (1998), which consisted of just a single home visit, the intervention group had fewer readmissions to hospital and spent fewer days in



hospital over the 6-month follow-up period than the control group. In contrast, in an intervention comprising follow-up at a nurse-monitored out-patient programme, in which clinic visits ranged from 1-14 and telephone follow-up averaged 4 per patient, the days spent in hospital over the 6-month study period were slightly higher in the intervention group, although the difference was not statistically significant (Ekman et al, 1998).

Riegel et al (2000) suggested that differences in outcomes may be related to differences in the patient populations. Their study used an unselected population whereas others have been more restricted to, for example, patients considered at high risk of readmission. When Riegel et al examined their findings by functional class, measured on the Specific Activity Scale (Goldman, Hasimoto, Cook & Loscalzo, 1981) they found that in those who had been least impaired at baseline (class I), the intervention group had more hospitalisations compared with controls whereas in those in higher functional classes (i.e. more impaired) the intervention and control groups did not differ. The intervention was most successful in reducing hospital days and total costs in the group of patients in functional class II i.e. those with minimal functional compromise. Other studies did not examine the efficacy of their intervention by functional class so comparison of this finding with other studies was not possible.

### **3.5.5 Discussion of systematic review findings**

In 2001, when the current study began, the delivery of care for people with heart failure had been undergoing a period of change. Shortcomings in the delivery of medical care had been recognised and disease management programmes had been introduced as a way of improving care. Most studies that had been published at that time, and which were included in this review, were evaluating the effectiveness of these new models of care delivery. This review has shown that the way in which this care was delivered

nevertheless varied considerably across studies, as did intervention efficacy. The most commonly assessed outcomes were hospital admission and mortality and findings generally favoured the intervention group, although they often did not reach statistical significance. Interventions were more often successful in reducing readmissions for heart failure than all-cause readmissions but none produced significant reductions in mortality.

An important question to emerge in this review was which type of intervention produced the greatest benefit. Heterogeneity in patient populations, standard care and the content, duration and delivery of interventions made comparison between studies and identification of the most effective interventions difficult and no single model of intervention emerged as consistently more successful than others. For example, it did not seem to be the case that one mode of delivery, such as home visit or clinic appointment was better than the other. As few interventions assessed behaviour, it was not possible to tell if one approach was better than another at promoting self-management and whether this had an impact on outcomes.

The work by Stewart et al (1998,1999) indicated that very brief interventions can be effective whereas other studies show that more intensive interventions may not be. The finding that less intensive interventions can result in significant benefits is important. Highly intensive interventions are expensive to implement and may not be feasible in all healthcare environments. If it is possible to achieve similar results with less intensive, and therefore less costly, interventions, there will be greater potential to make such interventions more widely available.

An important matter to emerge from this review was the nature of standard care provided to the control group. It is evident that there was considerable heterogeneity between studies in several components of standard care and optimal recommended

treatment was often not provided. This has implications for evaluating the impact of interventions because some may be comparing an intervention group to a control group who are receiving sub-optimal medical care whereas others may be making the comparison with a control group who are receiving much better medical care. The scope for improving outcomes in the latter case is likely to be more limited. There are also implications for the design of future interventions because there would seem to be no justification for designing interventions that do not first ensure that all participants receive medical treatment according to recommended guidelines. The goal should be to examine whether interventions can be designed which provide additional benefits over and above medical care that meets recommended guidelines.

One of the aims of this review was to evaluate the extent to which interventions promoted self-management. Shortcomings in patient self-management had been recognised as a contributor to poor health outcomes and the interventions included in this systematic review all incorporated an education component aimed at improving self-management. The review found some uniformity across studies in the behaviours taught in their education programmes. Most interventions stressed the importance of adherence to medication and self-monitoring for early signs of worsening heart failure. Dietary advice, usually including sodium restriction was also common. Few studies, however, addressed the psychological aspects of heart failure that could affect self-management.

Although the interventions aimed to improve patient performance of several self-management behaviours, the approach adopted was usually one of patient education rather than self-management. Most studies did not make explicit the theory or rationale that was behind the design of the educational components of their interventions. In general they did not indicate any awareness of the considerable literature on self-

management of chronic illness and few interventions reported the use of theoretical constructs. Most studies appeared to adopt a traditional educational approach, which assumes that it is sufficient to provide information about the recommended treatment regimen that patients are expected to follow. It is recognised in other chronic illnesses that while knowledge is necessary, it is usually not sufficient to change behaviour (e.g. Coates & Boore, 1996; Gibson et al., 2000), thus to enable patients to optimise self-management, other approaches are required. Nevertheless, few interventions reported using strategies to facilitate behaviour change, such as problem-solving strategies, nor did they report that healthcare professionals who delivered the interventions had received training in these techniques.

Another indication that self-management was not the main focus of these interventions was that few studies assessed self-management behaviours and, of those that did, few examined the relationship between these behaviours and health outcomes.

This review has shown that at the time of commencement of the current study, the promotion of self-management for patients with heart failure was still fairly undeveloped. While it is encouraging that the small number of studies that examined self-management behaviours reported positive findings, in general, the studies published up to February 2001 provided limited guidance in the development of self-management interventions for this patient population. At the time it remained necessary to develop interventions that specifically targeted self-management and evaluate whether it was possible to improve patients' self-management of their heart failure and if this in turn helped to improve health outcomes.

However, a number of important issues have emerged from this review:

- behaviours considered important in self-management of heart failure were identified
- the review identified a need to develop an intervention which could help to enhance self-management of heart failure
- the review found that an intervention of low intensity could produce significant benefits
- evaluation of a new intervention should involve comparison to a standard care control group who receive medical care according to established guidelines
- a single intervention model will not necessarily be applicable for all patients therefore evaluation of the intervention should include examination of which factors predict success of the intervention

The way in which these issues were incorporated into the intervention and study design are dealt with in more detail in the next two chapters.

Table 3.1 Description of studies

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
1	Bushnell 1992 USA	Pre-post	41 71 years 58% male	Patients admitted to medical teaching units of large acute care hospital with primary diagnosis of heart failure	<b>Self-care nursing intervention</b> - Two sessions before discharge included education booklet, review and testing of patient knowledge. Patient began weighing, self-monitoring and making dietary changes in hospital	6 months	<b>Mortality</b> - 34% died within 6 months  <b>All cause hospitalisations</b> - After 3 months, 16% had two or more readmissions, 26% had one readmission, 58% had no readmissions. After 6 months, 25% had one or more admissions (sic)
2	Rich et al 1993 USA	RCT	98 79 years 41% male	Admitted to a secondary and tertiary care university teaching hospital with HF at moderate or high risk of readmission. Mean NYHA : 2.7 Int 3.0 Con	1. <b>Comprehensive multidisciplinary treatment strategy</b> - Daily visits during hospital admission, 3 home visits in first week and then at regular intervals plus telephone contact. Included intensive education, detailed review of medications, simplifying regime where possible, early discharge planning, enhanced follow-up through home care and telephone contacts. 'Emotional support' provided in majority of cases but nature of this not described.  2. <b>Standard care</b> - all conventional treatments as requested by patient's attending physician which could include social service evaluation, dietary and medication teaching, home care, all other available hospital services	90 days post discharge	<b>All cause hospitalisations</b> - 45.7% controls vs. 33.3% intervention readmitted (n.s.) (Readmission rate was lower in moderate risk subgroup but not high-risk subgroup.) Average 4.8 days hospitalised. Intervention 1.4 fewer days than controls (n.s.). In moderate risk subgroup, intervention spent average 3.5 fewer days than controls (n.s.). In high risk subgroup, intervention spent 2.1 more days hospitalised than controls (n.s.)

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
3	Schneider et al 1993 USA	CT	54 72 years 50% male	Admitted with a diagnosis of HF to cardiac nursing unit of non-profit mid-western medical centre	<p><b>1. Medication discharge planning</b> – One 20min education session with patient and family member prior to discharge. Medication schedule to fit patient's routine. Discussion of possible problems and suggested solutions. Physician contact details given.</p> <p><b>2. Usual care</b> – included usual education offered by staff nurses on unit which was thought to vary between patients and to be haphazard.</p>	31 days	<b>All cause hospitalisations</b> - 2 intervention (7.7%) vs 8 control (28.6%) readmitted (p=.05)
4	Kostis et al 1994 USA	RCT	20 66 years 70% male	Patients with HF, NYHA II or III, LVEF ≤40%. Source of recruitment unclear	<p><b>1. Intensive lifestyle modification</b> – Group cognitive behavioural therapy 60-90 mins 2x per week for 12 weeks. Weekly meetings with dietician. Gradual increase in exercise over 3 week period to 1hr, 3 to 5 times per week at heart rate of 40 to 60% functional capacity.</p> <p><b>2. Digoxin</b></p> <p><b>3. Double-blind drug placebo</b></p>	12 weeks	<p><b>Mortality</b> - 1 death (17%) in placebo group.</p> <p>Anxiety and Depression – Improved significantly in Group 1 (p&lt;.05) but not in Groups 2 &amp; 3</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
5	Rich et al 1995 USA	RCT	282 median 79 years 37% male	Admitted to a secondary and tertiary care university teaching hospital with HF at risk of readmission. Mean NYHA 2.4	<p><b>1. Multidisciplinary intervention -</b> Intensive education about HF, individual dietary assessment and instruction, consultation with social services about discharge and care post discharge, medication analysis to simplify regime, intensive post discharge follow-up, individual home visits and telephone contact.</p> <p><b>2. Usual care -</b> all standard treatments and services ordered by their primary physicians. In no case was standard or generally accepted therapy withheld.</p>	90 days	<p><b>Mortality –</b> 13 (9.2%) intervention vs. 17 (12.1%) controls died within 90 days. Of these, 6 intervention and 2 controls had died prior to discharge from initial admission</p> <p><b>All cause hospitalisations -</b> 41 (28.9%) intervention vs. 59 (42.1%) controls had at least one readmission (p=.03). Total of 53 readmissions in Intervention vs. 94 in controls i.e. reduction of 44.4% (p=.02). Total days 556 Intervention vs. 865 Control (p=.04) This translates to 3.9 per patient in Intervention group vs. 6.2 per patient in Control</p> <p><b>HF hospitalisations – 24 readmissions in Intervention vs.</b> 54 in controls i.e. a reduction of 56.2% (p=.04). At 12 m follow-up, 80 readmissions in controls vs. 57 in intervention (p=.08)</p> <p><b>Admission free survival -</b> Survival for 90 days without readmission in 91 (64.1%) intervention vs. 75 (53.6%) controls (p=.09) BUT when analysis restricted to survivors of initial hospitalisation, 54.3% controls vs. 66.9% intervention survived without readmission (p=.04)</p> <p><b>Quality of Life –</b> (sub-sample n =126) - improved in both groups but significantly more in treatment group (p=.001)</p> <p><b>Behaviour -</b> Good compliance, defined as 80% taken correctly, was achieved by 82.5% in treatment group vs. 64.9% controls (p=.02)</p>



No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
6	Weinberger et al 1996 USA Study also included diabetes and COPD but only results for heart failure are reported here	RCT	504 63 years 98% male	Patients who had a diagnosis of HF (not necessarily the reason for admission) hospitalised at one of 9 Veteran Affairs Medical Centres NYHA: I, 12% II, 37% III, 33% IV, 18%	<p><b>1. Increased access to primary care</b> - Within 3 days before discharge, nurse assessed needs, listed medical problems, provided education materials, gave numbers of primary care nurse and physician. Doctor reviewed discharge plans, problems, medication regimes. Within 2 days post discharge, nurse phoned patient to assess difficulties with medication, health problems. Doctor and nurse reviewed and updated treatment plan at first post-discharge appointment.</p> <p><b>2. Usual care</b> – post discharge care provided by community physicians or at Veterans Affairs clinics, as arranged by in-patient physician</p>	6 months	<p><b>All cause hospitalisations</b> - 52.2% Intervention vs. 41.5% Control patients readmitted. Intervention had 0.27 readmissions per month vs. Control 0.15 per month. Intervention 11.7 days vs. Control 6.8 days (significance level not reported)</p> <p><b>Quality of Life</b> - scores were low at baseline and remained low throughout study period, n.s.d. between groups at either follow-up assessment period. BUT were not reported separately for HF</p>
7	Fonarow et al 1997 USA	Pre-post	214 52 years 81% male	Patients referred to cardiomyopathy centre for assessment for transplant. NYHA III, 44% IV, 56%	<b>Comprehensive management programme plus education</b> –weekly clinic follow-up until stable, systematic approach to drug therapy, education about diet, exercise, self-monitoring, emphasis on abstinence from alcohol and smoking. Follow-up by HF cardiologists in conjunction with referring physician		<p><b>Mortality</b> - 9 (4%) died within 6 mths</p> <p><b>All cause hospitalizations</b> - 26% of patients readmitted in 6 month follow-up period compared with 92% in the 6 mths prior to referral</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
8	Smith et al 1997 USA	Pre-post	21 61 years 100% male	New patients referred to cardiomyopathy clinic, with symptomatic CHF	1. <b>Cardiomyopathy clinic</b> - Frequency of clinic visits was determined by severity of CHF and need for medication titration, patients could be seen without appointment if they had exacerbation or ran out of medications. Nurse practitioner was available by telephone to answer any concerns	Post (after 6 months intervention period)	<b>Mortality</b> - 5%  <b>All cause hospitalisation</b> – number of hospitalisations reduced from 13 prior to intervention to <2 during study period (p=.017)  <b>Quality of Life</b> – improved over time (p=.001)
9	West et al 1997 USA	Pre-post	53 66 years 71% male	Patients hospitalised at Kaiser-Permanente medical centre in previous 12 months with primary or secondary diagnosis of HF or out-patients referred for HF treatment. NYHA: I 22% II 38% III 28% IV 12%	<b>MULTIFIT system</b> - Initial visit then weekly telephone contact for 6 weeks. Frequency of telephone contact thereafter depended on clinical status. – 3 objectives: - promote optimal dose of ACE inhibitors - promote daily sodium intake <2g - surveillance for signs, symptoms and laboratory evidence of worsening HF, and appropriate and efficient triage of patients demonstrating clinical instability. Clinical abnormalities prompted referral for urgent evaluation by primary physician	Average 138 ± 44 days	<b>Mortality</b> - 1(2%) died  <b>All cause hospitalisations</b> - 9 hospitalisations. Compared with the 12 mths before enrolment, total hospitalisation rates declined 74%, from 1.61 to 0.42/year (p=.0001)  <b>HF hospitalisations</b> - 3 hospitalisations. Compared with the 12 mths before enrollment, hospitalisation rates for HF declined 87%, from 1.12 to 0.15/year (p=.0001). Length of stay 4.3 ± 3.2 days  <b>Behaviour</b> - Sodium intake reduced by 38% (p<.0001)  <b>Quality of Life</b> – (n = 35) physical but not mental composite score improved at 6 mths (p=.01)

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
10	Cline et al 1998 Sweden	RCT	190 76 years 53% male	Admitted to University hospital, primarily for HF NYHA: III, 62% Mean 2.6	<p><b>1. Education and easy access clinic</b> - 2 x 30min in-patient sessions plus 1 x 60 min session for patient and family 2 weeks post discharge. Education, adherence emphasised, guidelines for self-mgt of diuretics, dairy of weight, swelling, symptoms, easy access clinic, nurse available by phone and at short notice. One prescheduled visit at 8 months post discharge. Nurse could schedule doctor visits when considered appropriate. Out-patient cardiology appt one and four months post discharge.</p> <p><b>2. Usual care</b> - out-patient follow-up by either cardiologists in private practice or primary care physicians as considered appropriate by discharging physician.</p>	12 months	<p><b>Mortality</b> – 30% Intervention vs. 28% Controls (p=.06)</p> <p><b>All cause hospitalisations</b> – 39% Intervention vs 54% Controls readmitted (p=.08). Mean hospitalisations per patient 0.7 Intervention vs 1.1 Control (p=.08). Mean days hospitalised 4.2 Intervention vs 8.2 Control (p=.07)</p> <p><b>Admission free survival</b> – 30% intervention vs 28% Control (n.s.)</p> <p><b>Time to first event/readmission</b> – Mean days to first readmission 141 Intervention vs. 106 Controls (p&lt;.05)</p> <p><b>Quality of Life</b> - No significant differences</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
11	Ekman et al 1998 Sweden	RCT	158 80 years 33% male	Admitted to medical wards of secondary care regional hospital with a discharge diagnosis of HF and/or cardiomyopathy. Those in need of specialist care treated in cardiology dept. Mean NYHA 3.2	<p><b>1. Structured-care nurse-monitored out-patient programme</b> - Intervention group contacted a week after discharge and offered a visit to clinic. 29% never visited the nurse. Number of visits ranged from 1 to 14. Telephone follow-up - median number of contacts 4 per patient. Patient's primary care provider and home health staff were continually informed about patient's situation by HF clinic nurse</p> <p><b>2. Usual care</b> - Current clinical practice which in general meant follow-up by GP and visit to ER if symptoms worsened.</p>	6 months	<p><b>Mortality</b> – 24% Intervention [BUT 16% of those who attended] vs 19% Controls (n.s.)</p> <p><b>All cause hospitalisation</b> – 61% Intervention [63% of those who attended] vs. 57% Controls readmitted (n.s.). Mean days hospitalised 26 Intervention [20 for those who attended] vs 18 Control (n.s.)</p> <p><b>Heart Failure hospitalisation</b> – 46% Intervention [50% of those who attended] vs. 49% Controls readmitted for heart failure (n.s.)</p> <p><b>Admission free survival</b> – 32% Intervention [36% of those who attended] vs. 39% Controls (n.s.)</p>
12	Serxner et al 1998 USA	RCT	109 71 years 48% male	Patients admitted to hospital 'large healthcare system' with a primary discharge diagnosis of HF	<p><b>1. Patient Education</b> – education materials mailed every 3 weeks x 4. Materials on CHF, medication, risk factors, behavioural health issues, coping with change, depression, stress</p> <p><b>2. Usual care</b> - normal and customary education in hospital but no special information once patients were discharged</p>	6 months	<p><b>Heart Failure hospitalisation</b> – 27% Intervention vs 50% Controls readmitted (<math>p &lt; .01</math>). Number of readmissions 21 Intervention (1.4 per patient) vs. 43 Control (1.59 per patient) (p not reported)</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
13	Shah et al 1998 USA	Pre-post	27 62 years 100% male	Patients recently discharged from hospital after admission with CHF and out-patients referred to HF clinic at Veterans Affairs Medical Centre with clinical evidence of HF for at least 6 mths. NYHA: II, 37% III/IV 63%	<b>Interactive Home Monitoring</b> - Education materials mailed weekly for 8 weeks covering information on CHF, medication, diet. Given BP monitor, weighing scale. Sent reminders re medication, weighing, BP and heart rate measurement. Telephoned once a week to ascertain clinical status. Given 24 hr access to nurse.	12 months (mean 8.5m)	<b>Mortality</b> – 4 (15%) died  <b>All cause hospitalisation</b> – Reduced from 0.8 to 0.4 per patient per year (n.s.). Days hospitalised reduced from 9.5 to 7.8 per patient per year (p<.05)  <b>Heart Failure hospitalisation</b> – Reduced from 0.8 to 0.7 per patient per year (n.s.)
14	Stewart et al 1998 Australia	RCT	97 75 years 48% male	Patients admitted to a tertiary referral hospital with congestive HF and impaired systolic function, intolerance to exercise and history of 1 or more admissions for acute HF. NYHA at discharge II:III:IV Intv 24:23:2 Control 24:20:2	<b>1. Home-based intervention</b> - Before discharge, nurse counselling about compliance and reporting clinical deterioration. One week post discharge, home visit and assessment by nurse and pharmacist – those with poor medication knowledge or compliance received remedial counselling, daily reminder routine, weekly pill containers, monitoring by caregiver, medication information and reminder card, referral to community pharmacist. Patients requiring medical review were referred to GP.  <b>2. Usual care</b> - review by GP or cardiologist within 2 weeks of discharge. (27% of controls were also receiving domiciliary care or community nurse visits)	6 months	<b>Mortality</b> – 12% Intervention vs. 25% Controls (n.s.)  <b>All cause hospitalisation</b> – 49% Intervention vs. 65% Control readmitted (n.s.). Number of readmissions 36 Intervention vs. 63 Control (p =.03). Days hospitalised 261 Intervention vs. 452 Control (p=.05)  <b>Heart failure hospitalisation – Zero</b> Intervention vs. 5 Control had 3 or more admissions for heart failure (p=.02)  <b>Admission free survival</b> – 0.8 Intervention vs. 0.4 Control unplanned readmission or death per patient (p=.03)  <b>Time to first event</b> – Intervention tended to be readmitted earlier (n.s.)

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
15	Gattis et al 1999 USA	RCT	181 Median age 71.5 (I) 63.0 (C) 68% male	All patients undergoing evaluation in cardiology clinic of university medical centre with diagnosis of HF NYHA on enrolment I 12.7% II 54.1% III 29.8% IV 3.3%	<b>1. Clinical pharmacist addition to heart failure team</b> – optimisation of heart failure medication in collaboration with physician, discussion and explanation of medication with patient then telephone follow-up after 2, 12 and 24 weeks. Patients could contact pharmacist to ask questions or if problems arose. If patients indicated continuing or worsening symptoms, pharmacist recommended they contact physician and pharmacist also contacted physician. <b>2. Usual Care</b> Patient assessment and education were provided by attending physician and/or physician assistant or nurse practitioner	Median 6 months	<b>Mortality</b> – 3% Intervention vs. 5% Control (n.s.)  <b>All cause hospitalisation</b> – excluding non-emergency or elective procedures, 19% Intervention vs. 33% Control readmitted (p not reported)  <b>Heart failure hospitalisation</b> – 1% Intervention vs. 12% Control readmitted for HF (p=.005). 9% Intervention vs. 25% Controls had <i>cardiovascular</i> admissions (p=.004)  <b>Admission free survival</b> - 68% Intervention vs. 60% Control survived without admission (n.s.), excluding non-emergency or elective procedures, 78% vs. 62% respectively.

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
16	Jaarsma et al 1999 Netherlands	RCT	179 73 years 58% male	Patients admitted to cardiology unit of university hospital. NYHA <i>during</i> admission III 17% III-IV 21% IV 61%	<p><b>1. Supportive Education</b> - In hospital, nurse assessed needs, provided education and support. Telephone call 1 week after discharge assessed potential problems. Home visit reinforced and continued education as needed by patient's situation. After the home visit, patients were advised to call their cardiologist, GP or emergency heart centre in case of difficulties.</p> <p><b>2. Usual care</b> - Standard care, some may have received information about medication and lifestyle, depending on HCP they encountered.</p>	9 months	<p><b>Mortality</b> – 26% Intervention vs. 17% Controls (p not reported)</p> <p><b>All cause hospitalisation</b> – 37% Intervention vs. 50% Control (p=.06). Days hospitalised 768 (mean 9) Intervention vs. 861 (mean 9) Control (n.s.)</p> <p><b>Cardiac hospitalisation</b> – 29% Intervention vs. 39% Control admitted (p=.096). Mean days hospitalised 5.1 Intervention vs. 7.1 Control (n.s.)</p> <p><b>Behaviour</b> - Appraisal of Self-care Agency Scale - n.s.d. between groups. Heart Failure Behaviour Scale - intervention group reported greater adherence to self-care behaviours at 1 month (p = .001) and 3 months (p = .005) but not 9 months (p= .106). Over time, both groups improved at 1 month (p&lt;.001) but this decreased thereafter, however intervention score remained higher at 9 mths than baseline.</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
17	Linne et al 1999 Sweden	RCT	130 70 years 64% male	Patients discharged from HF unit of university hospital NYHA I 8% II 66% III 22% IV 0% 4% not determined	<p>1. <b>Systematic education</b> - Approx 2 weeks post randomisation, 1hr group education re symptoms, self-adjustment of diuretics, information on drug treatment. One week later, pharmacist provided information on drugs, side effects. CD-ROM dealt with symptoms, signs and causes of impairment, drug info and side effects</p> <p>2. <b>Usual care</b> - At discharge, all patients receive conventional information about their disease, symptoms and medication by a doctor. Medication list and individual limits allowed for change in body weight are provided. All patients receive standardised information booklet, containing information on HF and its management, individually set limits for short-term change in body weight, to be followed by frequent checks of weight at home. All patients (intervention and control) have at least one visit to a HF nurse except for those who do not need close follow-up. After one or more visits, most patients are discharged to GP or cardiologists</p>	6.5 months	<p><b>Mortality</b> – 5% Intervention vs. 5% Control</p> <p><b>Knowledge</b> – Intervention group scored higher than controls on knowledge questionnaire at 6 months (p=.0051)</p>



No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
18	Luskin et al 1999 USA	Pre-post	14 75 years 50% male	Patients enrolled in university hospital cardiac rehabilitation exercise programme	<b>Stress Management</b> – 75 mins per week for 8 weeks out-patient group stress management training by psychotherapist.	1 week post intervention	<b>Quality of Life</b> – No significant difference
19	Stewart et al 1999 Australia	RCT	200 76 years 62% male	Patients admitted to tertiary referral centre under care of cardiologist with at least one previous admission for acute heart failure. NYHA: at discharge (%): II:III:IV intervention 42:46:12 control 48:43:9	<p>1. <b>Multidisciplinary home-based intervention</b> – Single home visit plus telephone calls at 3 and 6 months. Additional home visit if patient had 2 or more unplanned readmissions within 6 months of index admission. After comprehensive home assessment, patient and family received counselling, strategies to improve adherence, exercise plan, monitoring, flexible diuretic regimen. Report sent to GP, cardiologist. Increased pharmacist contact, home support services for some.</p> <p>2. <b>Usual care</b> - existing norms for discharge planning - inpatient and community-based contact with a cardiac rehabilitation nurse, dietician, social worker, pharmacist and community nurse where appropriate. All patients had appt with GP, cardiology out-patient clinic or both within 2 weeks of discharge and regular out-patient review undertaken throughout the follow-up period.</p>	6 months	<p><b>Mortality</b> – 18% Intervention vs. 28% Control (p=.098)</p> <p><b>All cause hospitalisation</b> – Number of readmissions 68 (.14 per month) Intervention vs. 118 (.34 per month) Control (p=.03). Days hospitalised 460 Intervention vs. 1174 Control (p=.02)</p> <p><b>Heart failure hospitalisation</b> – 50% Intervention vs. 49% Control admissions were for heart failure</p> <p><b>Admission free survival</b> – 51% Intervention vs. 38% Controls remained event free (p=.04). Beneficial effects remained at 9 months (p=.037)</p> <p><b>Quality of Life</b> - At 3 months, MLHF + SF36 physical improved more in intervention group (p = .04 + p = .02 respectively, no significant difference in SF36 mental health. No differences on any scale at 6 months</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
20	Varma et al 1999 Northern Ireland	RCT	83 76 years 41% male	Inpatients and out-patients from 3 hospitals with diagnosis of HF NYHA mean 2.2	<p><b>1. Structured pharmaceutical care</b> - Educated by research pharmacist in structured fashion about CHF, prescribed drugs and management of CHF symptoms. Physicians and community pharmacists contacted about project.</p> <p>2. Standard care, in-patient care not described but both groups were assessed 3-monthly at out-patient clinic</p>	12 months	<p><b>Mortality</b> – 17% died in each group</p> <p><b>Heart failure hospitalisations</b> – 33% Intervention vs. 66% Control readmitted (p=.006)</p> <p><b>Quality of Life</b> - SF-36 - in general Intervention tended to score better but only significant on subscale Physical Function at 9 mths (p=.009) and 12 mths (p=.03) BUT it had also been higher at baseline (p=.04). Intervention also scored better on Mental Health subscale at 9 mths and 12 mths (both p=.014). Intervention scored better on subscales Vitality (p=.04) and Social functioning (p=.015), only at 12 mths. MLHF - Intervention significantly better at 9 months but not baseline, 3, 6, 12mths.</p>

No	Authors, year and country	Design	Participants		Description of Intervention and Control	Follow-up period	Findings
			N (start) Mean age % Male	Patient group			
21	Riegel et al 2000 USA	Quasi-experimental	240 Intervention significantly older - 74.44 v 70.77 (p<.05) 45% male	'Unselected population' admitted with HF to 5 hospitals NYHA on admission I 0% II 11% III 51.9% IV 37.1%	<p><b>1. Multidisciplinary disease management</b> - to promote self-management using educational materials, in-hospital counselling by pharmacists and dieticians, discharge assessment by social work, outpatient support groups, physician collaboration, home visits by HF nurses, telephonic case management. All interactions focused on promoting self-care abilities. Improvements in physician practice patterns were targeted through educational efforts. Approx 7 home visits and 6 telephone calls per patient.</p> <p><b>2. Usual care</b> - managed by primary care physician or cardiologist without assistance of case manager. Staff nurses taught patients about HF during hospitalisation using AHA or pharmaceutical company brochures. Dietician and social worker were consulted in problematic situations. Some patients referred for routine home care.</p>	Post (after 6 months intervention period)	<p><b>Mortality</b> – 11% Intervention vs. 8% Control (p not reported)</p> <p><b>All cause hospitalisation</b> – Number of hospitalisations per patient .63 Intervention vs . 60 Control (n.s.). Days hospitalised 2.66 per patient Intervention vs. 3.03 Control (n.s.).</p> <p><b>Heart failure hospitalisation</b> - .32 hospitalisations per patient Intervention vs. .23 Control (n.s.). 1.31 days per patient Intervention vs. 1.08 Control (n.s.)</p>

Table 3.2 Intervention components

No	Authors and country	Year	Brief description of intervention	Components	Duration of intervention	Patient contacts			
						In hospital	Home visit	Out-patient	Telephone
1	Bushnell USA	1992	Self-care nursing intervention	Education Patient begin self-management in hospital	Complete by time of discharge	2 sessions			
2	Rich USA	1993	Comprehensive multidisciplinary treatment strategy	Education Review and simplification of medication regime Discharge planning Enhanced follow-up	ongoing	Daily visits	3 within first week post discharge then at regular intervals		Follow-up telephone calls made but frequency not reported
3	Schneider USA	1993	Medication discharge planning	Education Medication review with schedule adapted to patient's routine	Single, 20 minute session	1 session			
4	Kostis USA	1994	Intensive lifestyle modification	Group CBT Exercise Diet	12 weeks			CBT 60-90min 2x pw Weekly meetings with dietician Gradual increase in exercise over 3 weeks to 1hr 3x pw	

No	Authors and country	Year	Brief description of intervention	Components	Duration of intervention	Patient contacts			
						In hospital	Home visit	Out-patient	Telephone
5	Rich USA	1995	Multidisciplinary intervention	Education Dietary assessment and instruction Social services discharge consultation Medication review and simplifying Intensive follow-up	ongoing	Daily visits	3 within first week post discharge then at regular intervals		Follow-up telephone calls made but frequency not reported
6	Weinberger USA	1996	Increased access to primary care	Discharge planning, including discussion between primary and secondary care physicians Education Medication review	Ongoing	One visit from primary care nurse within 3 days before discharge, one visit from primary care physician within 2 days of discharge	None	Primary care clinic appointment within 1 week of discharge [Frequency of visits thereafter not reported]	First within 2 days post discharge. Over course of study patient received average 7.5 calls
7	Fonarow USA	1997	Comprehensive management programme plus education	Systematic approach to drug therapy Education Intensive follow-up				Weekly until stable	
8	Smith USA	1997	Cardiomyopathy clinic	Education Regular out-patient follow-up	ongoing			Frequency of clinic visits determined by severity and need for medication titration	Patients could telephone nurse about any concerns

No	Authors and country	Year	Brief description of intervention	Components	Duration of intervention	Patient contacts			
						In hospital	Home visit	Out-patient	Telephone
9	West USA	1997	MULTIFIT system	Optimise ACEi Promote restricted sodium intake Self-monitoring	Ongoing		One (but reporting unclear)		Weekly for 6 weeks then as needed
10	Cline Sweden	1998	Education and easy access clinic	Education Easy access clinic follow-up		2x 30 minute education sessions		1x 60min education session for patient and family. Easy access to nurse clinic as required Prescheduled nurse visit at 8mths Cardiology appt at one and four mths Nurse could schedule visit to doctor if required	
11	Ekman Sweden	1998	Structured-care nurse-monitored out-patient programme	Guidelines for nurse Education Goals set Out-patient follow-up	Ongoing			Offered clinic appointment. 29% of patients did not visit clinic. Number of visits ranged from 1 - 14	Median 4 contacts per patient

No	Authors and country	Year	Brief description of intervention	Components	Duration of intervention	Patient contacts			
						In hospital	Home visit	Out-patient	Telephone
12	Serxner USA	1998	Patient Education	Education	12 weeks			4 sets of patient education materials mailed at 3 weekly intervals	
13	Shah USA	1998	Interactive Home Monitoring	Education Home monitoring	8 weeks			Education materials mailed weekly	Telephoned weekly to ascertain clinical status. Patient had 24hr access to nurse
14	Stewart Australia	1998	Home-based intervention	Education Home visit by nurse and pharmacist Referral to community pharmacist	1 week post discharge	One session	One visit one week post discharge		
15	Gattis USA	1999	Clinical pharmacist addition to heart failure team	Education Optimising medication	24 weeks			Single education and review from pharmacist	2, 12, 24 weeks
16	Jaarsma Netherlands	1999	Supportive Education	Education Needs assessment		About 4 sessions	One visit within 10 days of discharge		One within 3 days of discharge

No	Authors and country	Year	Brief description of intervention	Components	Duration of intervention	Patient contacts			
						In hospital	Home visit	Out-patient	Telephone
17	Linne Sweden	1999	Systematic education	Education	3 weeks			1 hour group education approximately 2 weeks post enrolment. Individual session 1 week later	
18	Luskin	1999	Stress management	Stress management	8 weeks			75mins pw x 8 weeks	
19	Stewart Australia	1999	Multidisciplinary home-based intervention	Comprehensive home assessment Education Flexible diuretic regimen Increased pharmacist contact Home support services for some	6 months		One home visit 7-14 days post discharge. Additional visit if patient had 2 or more unplanned readmissions within 6 months		3 mths, 6 mths
20	Varma Northern Ireland	1999	Structured pharmaceutical care	Education	Seems to have been a single session but not clear where				
21	Riegel USA	2000	1. Multidisciplinary disease management	Education Discharge planning Support group Home visit Telephonic case management	6 months	Number of sessions unclear	Approx 7 visits		Approx 6 calls



Table 3.3 Behaviours addressed

No	Study	Behaviours addressed														
		Sodium restriction	Weight monitoring	Medication adherence	Symptom monitoring	Flexible diuretic regimen	Fluid balance	Pacing rest and activity	Exercise	Diet, general	Weight loss	Smoking cessation	Alcohol abstinence	Relaxation	Coping	Accessing health care
1	Bushnell 1992	X	X	X	X			X								
2	Rich 1993	X	X	X												
3	Schneider 1993			X												
4	Kostis 1994	X							X	X	X	X	X	X	X	
5	Rich 1995	X	X	X						X						
6	Weinberger 1996	Not clear														
7	Fonarow 1997	X	X		X	X	X		X							
8	Smith 1999		X	X		X				X						
9	West 1997	X	X	X	X				X	X		X	X			
10	Cline 1998		X	X	X	X										
11	Ekman 1998		X	X	X					X						
12	Serxner 1998		X	X						X					X	
13	Shah 1998		X	X	X					X						
14	Stewart 1998			X	X											
15	Gattis 1999			X												
16	Jaarsma 1999	X	X	X	X		X	X							X	X
17	Linne 1999			X		X	X									
18	Luskin 1999														X	
19	Stewart 1999	X	X	X		X			X							
20	Varma 1999		X	X	X	X										
21	Riegel 2000	X	X	X	X				X							
	Total	9	14	17	10	6	3	2	5	7	1	2	2	1	4	1

## **CHAPTER 4**

### **DEVELOPMENT OF A SELF-MANAGEMENT INTERVENTION FOR PATIENTS ADMITTED TO HOSPITAL WITH HEART FAILURE**

This chapter describes the development of the self-management intervention. The development involved a review of the literature, described in the previous chapters, consultation with health professionals, training of a nurse to deliver the intervention and a pilot phase.

#### **4.1 Development team**

Development of the intervention was a collaboration between the Cardiovascular Medicine department of the Whittington Hospital NHS Trust and University College London Centre for Behavioural and Social Sciences in Medicine. The development team consisted of two health psychologists, a consultant cardiologist and a heart failure nurse specialist. The team met on several occasions during the development stage to discuss,

- a) patients to be included in the study
- b) the nature of care provided to the control group
- c) content and delivery of the intervention

Patient input was obtained during the pilot phase of the intervention.

#### **4.2 Objectives**

Chapter 2 provided an overview of the poor health outcomes experienced by people with heart failure, which include high mortality, repeated unplanned hospital admissions and poor quality of life. The objective of the study was to develop an intervention that could improve these outcomes.

When this study began, most of the interventions that had been implemented in heart failure were disease management programmes and many involved intensive case management. This type of management makes considerable demands on health care resources and therefore may be limited in the extent to which it can be implemented throughout the health care system. As the number of patients with heart failure increases, a service that offers intensive case management to all patients is likely to reach a point where it becomes more and more difficult to sustain. In this study, an important objective was to develop a brief intervention that could be delivered within the resources available to most hospitals.

Intensive case management also overlooks the role that patients play in managing their illness and has the potential to make patients more dependent upon the hospital and health care professionals. An important objective in designing the intervention in this study was to encourage patient self-management.

### **4.3 Study population**

Patients admitted to hospital with heart failure were considered to be the most appropriate group to target because they are known to be at high risk of early readmission to hospital and death and they consume immense NHS resources (see Chapter 2). Cleland, Swedberg, Solal et al, (2000) asserted that a hospital admission is a critical event because diagnosis and management are likely to be revised. They reported that up to 80% of first-diagnoses of heart failure occur at the time of hospitalisation and one-third of patients with heart failure will be hospitalised within any given year. Accessing such patients at this time would seem to be important not only because of the high frequency of later hospitalisation but it was also considered that a hospital admission may be a trigger for patients newly diagnosed with heart failure to initiate self-management behaviours and for patients with existing heart failure to

review their self-management behaviours and possibly be more open to making changes.

The literature reviewed in Chapter 3 indicated that demographic factors were unlikely to influence self-management therefore the intervention in this thesis was designed to be applied to all heart failure patients regardless of age, gender and other demographic factors. There was a suggestion from one study (Riegel et al, 2000) that patients may show a differential response to a multidisciplinary self-management programme according to their functional status. This was a post-hoc analysis and one that was not performed in other studies, therefore while it would be of interest to examine how patients in different functional classes respond, the current intervention was to be designed to target as broad a selection of the hospital in-patient heart failure population as possible.

## **4.4 Intervention development**

A number of different elements contributed to the development of the intervention. These included the literature on heart failure and self-management, clinical guidelines for the treatment of heart failure, the literature on self-management in other chronic illnesses, the conceptual basis of self-management interventions as well as a number of practical considerations.

### **4.4.1 Content of the intervention**

The content of the intervention i.e. the components to be targeted, were based on the literature on heart failure and self-management and the clinical guidelines for the treatment of heart failure.

The literature reviewed in Chapter 2 highlighted shortcomings in patients' self-management of heart failure and indicated that these shortcomings were associated with a greater risk of admission to hospital. These studies support the need for an intervention that can facilitate adoption and maintenance of self-management behaviours.

The literature reviewed in Chapters 2 and 3 provided some consensus about the self-management behaviours that should be targeted, with most interventions addressing adherence to medication and self-monitoring. Another important source of input regarding the areas to be covered in the self-management intervention was the heart failure guidelines (Task Force of the Working Group on Heart Failure of the European Society of Cardiology 1997; Scottish Intercollegiate Guidelines Network 1999) which outline several behaviours that are recommended for patients to adopt (see section 2.5.3). A poor understanding of heart failure and its treatment also emerged in the literature as a possible cause of poor self-management.

The literature review and clinical guidelines thus identified a number of factors that were related to health outcomes in heart failure and which were considered important to include in the intervention. These were:

#### **4.4.1.1 Understanding of heart failure, its signs, symptoms and treatment**

Some studies had indicated that patients had a poor understanding of their treatment regime. Concern was also expressed in the intervention development team that patients are not always given a clear explanation of their diagnosis and many interpret the information that there is a build up of fluid in their lungs as indicative of lung, not heart, disease. Misconceptions about heart failure have also since been reported by Horowitz, Rein & Leventhal, (2004). It was therefore considered important that patients' understanding of heart failure and its treatment should be explored and clarified where

appropriate. A clear understanding of heart failure is considered necessary for patients to place their symptoms and behaviours into context i.e. patients need to understand how heart failure leads to fluid build-up and how their behaviours such as medication and salt and fluid intake influence fluid balance.

#### **4.4.1.2 Adherence to medication**

Non-adherence to medication had been identified as a factor precipitating readmission to hospital and therefore was considered an important aspect to address in the intervention. As non-adherence to medication can be intentional (e.g. discontinuing medication once one is feeling better) or unintentional (e.g. forgetting to take medication) (Vermeire, Hearnshaw, van Royen & Denekens, 2001), it was considered important that the intervention should aim to address both causes.

#### **4.4.1.3 Fluid balance**

Maintaining a stable fluid balance is an important part of heart failure self-management. In addition to taking medication, avoiding fluid build up through excessive salt or fluid intake were considered important topics for inclusion in the intervention.

#### **4.4.1.4 Self-monitoring for early signs of deterioration**

Self-monitoring has been described as the foundation of self-management (Creer 2000). It not only provides the information on which patients base self-management decisions but also shows if self-management objectives have been achieved.

Heart failure can deteriorate rapidly and research has shown that patients often delay in seeking medical intervention. This delay means that patients have often deteriorated to such an extent that they require long hospital stays to restore clinical stability. Self-monitoring to identify early signs of deterioration has the potential to help to prevent further decline by enabling action to be taken at an early stage when re-stabilisation is

easier. Self-monitoring of signs of fluid retention through weight monitoring and checking for oedema were therefore considered important components of the intervention.

#### **4.4.1.5 Lifestyle changes**

Lifestyle factors that are considered important in heart failure include smoking cessation, minimal alcohol intake and regular physical activity. Although smoking cessation would be encouraged, it was not seen as a specific target of the intervention as it was considered likely to require more intensive specialist intervention that could not be accommodated in a brief self-management intervention as planned for this study. Patients with current alcohol addiction were excluded from the study however those who drank more than recommended limits but stated that they intended to cut down were included. Physical activity has been shown to be beneficial in heart failure (McKelvie, Teo, McCartney et al, 1995) but patients may restrict their activity because of breathlessness, a belief that they are unable to take exercise or fear of exacerbating symptoms. Encouragement to remain physically active or to increase activity as appropriate was considered an important matter for inclusion in the intervention.

#### **4.4.1.6 Mood**

While the potential influence of mood on self-management was acknowledged, mood was not considered a primary target of this intervention. This decision was taken because the intervention was designed to be brief and was therefore limited in the scope of components it could include. Hence the decision was made to focus on behaviours and cognitions as opposed to mood. It was also considered that strategies to directly address emotions would have required additional time plus additional skills from the intervention facilitator. An intervention specifically directed to address mood in heart failure would have been very different from the one in this thesis. Mood was rather considered as a dimension that potentially can be influenced by improvements in

patients' ability to self-manage their heart failure, achieved through changes in behaviour and cognitions and their perception of increased abilities to manage their condition.

#### **4.4.2 Facilitating change**

As reported in the sections above, the components to be targeted in the intervention comprised behaviours and cognitions. Although many heart failure interventions have targeted these and other self-management behaviours, they have adopted an information-giving approach which assumes that increased knowledge will lead to behaviour change. However, research in heart failure has shown that there is not a strong association between knowledge of the recommended heart failure self-management behaviours and their performance. It is also important that previous intervention studies have rarely measured behaviour or behaviour change therefore the impact of the intervention on behaviour and the impact of behaviour on outcomes in these studies is not known. With regards to an examination of cognition in relation to heart failure, the literature review identified only one study that examined cognitive factors in relation to heart failure management (Ni et al, 1999). Consequently, although the literature in heart failure provided guidance about which aspects of self-management needed to be targeted, it provided little guidance about the best approach to adopt in order to enhance self-management as interventions have relied on provision of information rather than being informed by theories of behaviour and behaviour change (see section 3.5).

An important consideration in developing the intervention was thus to choose the methods which were most likely to facilitate change in these behaviours and cognitions. This was informed by the literature on self-management and health psychology theory. The literature on health psychology theories, as outlined in chapter 3, proposes that



important determinants of self-management behaviour are the beliefs that people hold about their illness and its treatment (the self-regulatory model), and their self-efficacy in their ability to perform the behaviours (social cognitive theory). Although only a small amount of research has examined these factors in heart failure (see section 3.4), the findings offer some evidence for their importance.

The literature from self-management in other chronic illnesses provides additional guidance on how to enhance self-management. A full review of the considerable literature on self-management in chronic illness is beyond the scope of this thesis but reviews in other illnesses have been examined. A consistent finding from the reviews was that interventions which provided patients solely with information were ineffective (Coates et al., 1996; Taal, Rasker & Wiegman, 1997; Gibson et al., 2000a). However, interventions that incorporated behavioural techniques were more successful. In asthma, a Cochrane review (Gibson, Coughlan, Wilson et al, 2000b) identified three components that seemed to be important in reducing asthma exacerbations. These were self-monitoring for early signs of problems, regular review by clinicians and use of written action plans for managing symptoms. Literature on self-management of diabetes has indicated that theoretically-based interventions, particularly those based on social learning theory, tend to be more effective than educational approaches (Griffin, Kinmouth, Skinner & Kelly, 1998). Self-efficacy has also been identified as an important influence on outcomes in arthritis (Taal et al, 1997).

In summary, the literature from other chronic illnesses demonstrates that an intervention which simply provides patients with information about their illness and its management is unlikely to improve their self-management whereas inclusion of other components such as self-monitoring and strategies to facilitate behaviour change appear to be important.

Based on the literature summarised above, the key concepts that embrace both behavioural and cognitive aspects of behaviour change and thus would form the basis of this self-management intervention were considered to be:

- The inclusion of clear behavioural goals and self-monitoring
- The concept of self-efficacy
- the potential role of illness and treatment beliefs as factors that may influence the adoption of self-management behaviours

These are considered further in the following sections.

#### **4.4.2.1 Behavioural goals and self-monitoring**

The behavioural goals of the intervention were based on the behaviours highlighted in section 4.5.1 above i.e. adherence to medication, fluid balance, lifestyle changes and self-monitoring for early signs of deterioration.

In the case of self-monitoring, the intervention included skills training in how to self-monitor effectively for signs of deterioration and an action plan for the magnitude of change which should trigger contact with the health care service so that remedial action could be taken. The use of similar types of action plan in asthma have been found to improve outcomes (Gibson et al, 2000b).

In the case of medication adherence, it was considered appropriate to help facilitate participants to take all their medication as prescribed. The intervention thus involved identification of factors that could act as barriers to taking medication and aimed to help participants overcome these (see sections 4.5.2.2 and 4.5.2.3 below ).

In the case of fluid intake, the heart failure guidelines provide an approximate fluid intake that is recommended and the intervention used this as a guide. Participants

however decided on how to manage their fluid intake throughout the day. Similarly with salt intake, the heart failure guidelines suggest a maximum daily salt intake, so the intervention was designed to assist participants to identify their current salt intake and whether reduction was recommended and encourage them to decide on how to reduce their salt intake if necessary.

Physical activity levels were likely to vary considerably between participants therefore the goal of the intervention was for participants to maintain or increase physical activity levels as appropriate. The intervention was designed to help patients plan how they would incorporate physical activity into their day.

Many self-management interventions include formal goal-setting and contracting sessions in which participants set goals for the changes they intend to make, and write contracts for the performance of those behaviours (e.g. Lorig et al, 1999). Over a period of several weeks, participants can increase these goals and set goals for new behaviours. Given the time-limited nature of the intervention in this study, this process was not considered feasible. Furthermore, this process is more suitable for some behaviours than others. For example, it is suitable for encouraging increasing physical activity over time. However, taking medication as prescribed is essential to prevent heart failure deterioration and as such, it would be inappropriate for a self-management intervention to facilitate goal-setting for anything other than complete adherence. As such, taking medication as prescribed was a predefined goal of the intervention. Rather than choosing one or two behavioural goals, patients were encouraged to perform all the behaviours included in this intervention. As the intervention was designed to be brief, it incorporated only a small number of behaviours, all of which are recommended according to heart failure management guidelines (see section 2.5.3). Patients were however actively involved in planning and deciding how to integrate the behaviours into their daily lives therefore they were involved in deciding how the goals were

implemented. For example, participants would decide if they were going to try to reduce the salt in their diet and if so, how they would do it e.g. by cutting out/down on certain foods, stopping adding salt to cooking and/or to the food on their plate and so on. Similarly, in the case of exercise, participants were actively involved in deciding what and how much activity they would do and how they would integrate it into their daily life.

#### **4.4.2.2 Self-efficacy**

The literature in self-management and in behaviour change more generally has shown the importance of enhancing self-efficacy to facilitate change. Key to enhancing self-efficacy is mastery experiences (see section 3.2.2), as success in performing a behaviour increases the likelihood that it will continue, whereas failure undermines self-efficacy and discourages the behaviour. An important aspect of the intervention was therefore to promote mastery by helping participants to overcome any factors that could act as barriers to performing the behaviour.

The problem-solving approach of D'Zurilla & Goldfried (1971) (see section 3.3.5) was considered suitable for this purpose. Hence for each behavioural goal of the intervention, participants would make the decision on how best to perform the behaviour by identifying any problems to implementing it and choosing a strategy that they considered would be most effective for overcoming any difficulties. After implementing this strategy they would review its effectiveness and adapt it or try a new strategy as appropriate.

It was anticipated that some of the problems that participants would identify in adopting and maintaining self-management behaviours would involve difficulty in understanding and remembering when and how to perform them. Such factors could give rise to unintentional non-adherence. Therefore medication and self-monitoring charts were

offered and participants were provided with a booklet as an aide memoir (Appendix B). The intervention facilitator could also suggest some possible strategies based on stimulus control (see section 3.3.4) to help participants to remember, such as establishing a link between taking medication and a routine such as brushing one's teeth. Participants could then decide whether or not they considered this a useful general strategy to adopt and how they would adapt this to their lifestyle and circumstances.

#### **4.4.2.3 Illness and treatment beliefs**

Although the literature which has examined patients' beliefs about heart failure is very limited, it suggests that patients hold a poor understanding of the illness and its treatment. Furthermore, studies of the self-regulatory model (see section 3.2.1) indicate that patients' beliefs influence how they manage their illness. Accordingly it was considered important that patients' beliefs about their illness and treatment should be elicited as part of the intervention. Misconceptions could then be corrected and unhelpful beliefs could be challenged. Strategies for challenging beliefs are drawn from cognitive restructuring techniques (see section 3.3.6).

#### **4.4.3 Practical and clinical issues**

Several practical and clinical considerations were taken into account when designing the intervention.

##### **4.4.3.1 Structure and duration of the intervention**

As mentioned above, an important aim was to develop a brief and therefore potentially cost effective intervention. It was decided that a minimum of three sessions was necessary. The first session would involve introduction of the self-management tasks. After a period in which patients would have the opportunity to put the self-management

intervention into practice, the second session would review any problems encountered and examine ways to overcome them. A third session would then provide the opportunity to review progress.

Given that heart failure can deteriorate rapidly, it was considered important to initiate the intervention in hospital so that patients could practice some of the behaviours during their hospital stay and would be ready to continue them in their own home. It was therefore planned to schedule the first session prior to discharge from hospital. The heart failure nurse specialist on the development team considered that a single meeting prior to discharge would be insufficient to develop a relationship with the patient so a brief introductory session was added to this part of the intervention. Follow-up in the early period post discharge was considered necessary to review progress and address any problems that arose in the immediate post discharge period. A home visit one week after discharge was chosen as this enabled early review and could be useful for identifying problems that arose in the home environment. It was decided that the final session which reviewed progress after the home visit should be by telephone thus helping to optimise efficiency of healthcare resources.

#### **4.4.3.2 Mode of delivery**

As patients were to be seen first during their hospital stay and later in their own home, the intervention was designed to be delivered to patients individually rather than as a group programme.

#### **4.4.3.3 Who should deliver the intervention?**

In deciding who should deliver the intervention it was taken into account that the intervention would include disease-specific information as well as self-management techniques. While a psychologist may be considered to be the health professional best qualified to deliver the aspects of a self-management intervention that deal with beliefs

and behaviour change, a nurse would be more appropriate for other aspects of the intervention. Furthermore, the generalisability of the intervention to other environments would be more limited if it required a psychologist. The requirement was to design a brief intervention which for practical purposes could be delivered by a single health professional. Other health professionals and lay people have been trained to deliver self-management interventions (Newman, Mulligan & Steed, 2001), therefore it was decided that the most appropriate option was to train a heart failure nurse specialist in self-management techniques. This would also have the benefit that integration of such an intervention into routine heart failure care would be fairly straightforward.

#### **4.4.3.4 Clinical care**

Ideally from the perspective of evaluating the self-management intervention, clinical care would have been completely separate from the intervention so that the only difference between the care received by the intervention and control groups would have been the self-management intervention. However in practice this was not possible. As the heart failure nurse was to visit patients at home following discharge from hospital it was considered ethically necessary to include a clinical examination during the visit and to take action as clinically appropriate.

Also, patients were being asked to self-monitor for early signs of deteriorating heart failure therefore it was important for them to have rapid access to a health care professional who could offer appropriate clinical input. It was therefore decided to advise patients to contact the heart failure nurse if they identified indicators of deterioration.

## 4.5 Manual (Appendix A)

Self-management interventions are usually complex and the many interventions that have been developed in several chronic illnesses vary considerably. This can make comparison of interventions difficult as the ways in which they differ are not always clear from journal reports. Journal word restrictions mean that interventions can not be fully reported but it is important that the intervention is described in detail elsewhere so that it can be replicated. For this reason it was considered important to describe the intervention in detail in a facilitator's manual. The manual was not designed to be used on its own but as a supplement to the training sessions which are described below.

The manual for this intervention was divided into two sections

- a) the skills that the nurse would need to use to facilitate behaviour change including the manner of interaction with patients, problem-solving strategies and eliciting and challenging unhelpful beliefs
- b) the procedures for each session of the intervention..This section of the manual set out in detail what was to be covered in each session. It set out the objectives of each session and the behaviours that were to be addressed. It also offered suggestions on the types of open questions that could be used to elicit information about the difficulties patients were having in adopting self-management behaviours and about their beliefs about the illness and its treatment.



## **4.6 Nurse training**

### **4.6.1 Difference between usual nursing practise and delivering a self-management intervention**

An important difference between usual nursing practice and a self-management intervention is the general relationship with the patient. In the former, the nurse often provides information i.e. advises the patient what to do, whereas the latter requires a more open, enquiring approach to try to elicit and understand how the patients think and feel about their heart failure. The relationship is more like a partnership than the teacher-pupil relationship of the traditional educational model. In their traditional caring role nurses may try to solve problems for patients but in a self-management intervention, the role of the nurse is to act as a facilitator to help patients find their own solutions. It is important for the nurse to resist the temptation to suggest what may seem obvious solutions.

Whitehead (2001) commented that nurses “are often unaware of the extremely complex human phenomena associated with modifying health-related behaviours...”. The traditional educational approach that is usually adopted in nursing practice assumes that knowledge of appropriate health behaviour will be sufficient to bring about behaviour change. It was therefore important that the nurse should recognise the limitations of a traditional educational approach and gain an understanding of the role of psychosocial factors in behaviour change.

Delivering a self-management intervention also entails specialist skills that are not taught as part of routine nursing training. The nurse therefore required training in skills to facilitate behaviour change such as problem-solving techniques and how to elicit and challenge patients' beliefs.

#### **4.6.2 Aim and content of training sessions**

The aim of the training sessions was to teach the nurse the skills required to deliver the self-management intervention. Training sessions took place before starting the intervention, then, periodically over the course of the implementation period, sessions were held to review and refresh the nurse's skills. In all, approximately 15 hours of training was given. Training was conducted by two health psychologists, including the author.

The nurse was given a background to self-management theory and factors influencing behaviour change. A series of role plays was used to teach the skills required to deliver the intervention. These included asking open questions to elicit patients' beliefs and understanding about their illness and treatment, the use of problem-solving techniques and how to challenge beliefs. In the role plays, the nurse practiced delivering the intervention to one of the health psychologists who took the role of the patient. The other health psychologist observed and provided feedback. One of these sessions was video recorded and feedback provided.

The nurse had the opportunity to practice using these skills with patients during the pilot phase of the study. She reported on her experiences with each patient in the pilot phase and training sessions provided an opportunity to examine any difficulties that were encountered and to review the acquisition of self-management facilitation skills.

Following the pilot phase, the nurse began delivering the intervention using the intervention manual. Training sessions were held approximately 3 monthly during the course of the intervention. These involved the nurse feeding back her experiences of working with different patients and the difficulties she had encountered as well as examples of situations she felt had been dealt with effectively. One important feature of

the training was for the trainers to model the techniques that were being taught in the training sessions. For example when the nurse brought a problem to the session, it was dealt with by using problem-solving techniques.

## **4.7 Pilot phase**

The intervention was piloted with 10 patients. The patients gave positive feedback about the intervention and were pleased with the nurse's input. They did not offer any suggestions about how the intervention should be changed. The nurse did not suggest any changes to the content of the intervention based on the pilot phase. Outcomes for patients who participated in the pilot phase are not included in the results sections of the study.

## **4.8 Standard care control group**

The focus of many of the interventions that have been developed in heart failure is on more intensive healthcare professional input to achieve optimal medical care i.e. care according to published medical guidelines. This study did not wish to confound optimising of medical care with self-management therefore it was considered crucial in this study that the intervention group should be compared to a control group who received optimal medical care. In addition, given that optimising medical care has been demonstrated to lead to improved outcomes, it was also considered unethical to do otherwise. Therefore all study patients received standard information about their diagnosis, that they received care according to recommended guidelines while in hospital and regular cardiology follow-up after discharge. The only aspect of care which was designed to differ between the intervention and control group was the self-management intervention.

As part of its heart failure service, the hospital aimed to optimise its standard care for all patients admitted with heart failure. Hospital admissions records were examined every week day and all patients with symptoms on admission that could have indicated heart failure were reviewed by the cardiology clinical research fellow from the study team. Patients who had signs and symptoms of heart failure received an echocardiographic examination to confirm the diagnosis. Patients who were admitted to cardiology wards were under the sole care of the cardiology team and those who were admitted to medical wards received shared care, meaning that they were managed on a day-to-day basis by their physicians with frequent input from the cardiology clinical research fellow and the consultant cardiologist where necessary. Weekly meetings were held with the consultant cardiologist on the study team to discuss the management of all patients. Medical treatment followed a standard protocol (Appendix C). Patients were not discharged from hospital until their medication and clinical condition i.e. weight, symptoms and renal function had remained stable for two days. All patients received out-patient follow-up by a cardiologist within 6-8 weeks post discharge and thereafter as necessary. To ensure that intervention and control group patients received the same medical care, the cardiologists who provided follow-up care and conducted the clinical assessments were not advised of study group allocation. Patients in the control group had no contact with the heart failure nurse. All patients received the hospital's standard heart failure leaflet, which included information about heart failure and its treatment (Appendix D). A summary of the components of both the intervention and control groups are shown in Table 4.1.

Table 4.1 A summary of the components of the intervention and control conditions

Standard care control group	Intervention group
1. Medical treatment according to protocol	1. Medical treatment according to protocol
2. Hospital information leaflet which included: <ul style="list-style-type: none"> <li>- a definition of heart failure</li> <li>- information about its signs and symptoms</li> <li>- information about medication and surgery</li> <li>- advice on lifestyle change – to lose weight if necessary, avoid salt, change fluid intake, not smoke, keep active and moderate alcohol intake</li> </ul>	2. Hospital information leaflet which included: <ul style="list-style-type: none"> <li>- a definition of heart failure</li> <li>- information about its signs and symptoms</li> <li>- information about medication and surgery</li> <li>- advice on lifestyle change – to lose weight if necessary, avoid salt, change fluid intake, not smoke, keep active and moderate alcohol intake</li> </ul>
	3. Intervention based on self-management principles to facilitate: <ul style="list-style-type: none"> <li>- adherence to medication</li> <li>- self-monitoring for early signs of deterioration</li> <li>- fluid management</li> <li>- reduced salt intake</li> <li>- physical activity</li> </ul>

## **CHAPTER 5**

### **METHODS**

#### **5.1 Aim**

The aim of this study was to design a brief self-management intervention for patients admitted to hospital with heart failure and to evaluate its effectiveness in a randomised controlled trial.

#### **5.2 Hypotheses**

It was hypothesised that

1. Patients in the intervention group would report better performance of self-management behaviours i.e. adherence to medication, self-monitoring for early signs of deterioration, salt and fluid management and physical activity.
2. Patients in the intervention group would experience lower rates of readmission to hospital than the standard care control group in the 90 days and 12 months following discharge from the index admission and lower 12-month mortality.
3. Patients in the intervention group would report better quality of life and mood than the standard care control group at 6-8 weeks and 12 months following discharge from the index admission.
4. The effect of the intervention on health outcomes would be mediated by changes in self-management behaviour, self-efficacy and illness and medication beliefs.

#### **5.3 Ethical approval**

Ethical approval for the study was sought from and granted by the Ethics Committee of the Whittington Hospital.

## **5.4 Design**

The self-management intervention was evaluated in a randomised controlled trial. A between-subjects repeated measures design was used.

## **5.5 Setting**

The study was conducted in the Whittington Hospital, a District General Hospital in North London.

## **5.6 Participants**

Patients aged  $\geq 18$  years (with no upper age limit) who were admitted to the Whittington Hospital NHS Trust, with a primary or secondary diagnosis of heart failure due to left ventricular systolic dysfunction were eligible for the study.

Heart failure was diagnosed using the European Society of Cardiology definition (Remme & Swedberg, 2001) i.e.

- symptoms of heart failure (breathlessness, fatigue, ankle oedema) at rest or in exercise and
- objective evidence of cardiac dysfunction at rest [usually echocardiogram] and
- in cases where the diagnosis is in doubt, response to treatment directed towards heart failure.

Patients who were admitted with symptoms of heart failure (breathlessness, fatigue, ankle oedema) and had ECG evidence of uncontrolled atrial fibrillation (ventricular response  $> 100$  bpm), and responded to treatment directed towards heart failure, were also eligible because in these circumstances echocardiographic assessment of left ventricular function is unreliable.

Patients were excluded from the study if they

- did not speak sufficient English to understand the intervention and assessments
- had a severe psychiatric disorder, cognitive impairment (learning disability, dementia or Abbreviated Mini Mental (Hodkinson, 1972) score of less than 7 out of 10) or physical disability which would have made completion of the assessments and/or participation in the intervention difficult or impossible
- had severe alcohol or drug abuse
- had suffered an ST elevation myocardial infarction within 3 months of admission to hospital
- had another life-threatening illness such as end stage malignant disease
- lived outside the hospital catchment area where a home visit would be unfeasible.
- were being discharged to, or followed up by, another hospital
- were being discharged to long-term residential care

## **5.7 Study outcomes**

The primary study outcomes were the number of unplanned hospital readmissions and the days spent in hospital in the 90 days post discharge from the index admission (including admission to hospitals other than the study hospital). In this context, unplanned readmission refers to admissions other than for elective procedures. Secondary outcomes were mortality in the 90 days post discharge from the index admission, the number and duration of hospital admissions and mortality in the 12 months post discharge, mood and quality of life.

Process or mediator variables are those through which the intervention may be expected to influence outcomes i.e. behaviours and cognitions. The process variables



assessed included self-management behaviours and beliefs about self-efficacy, the illness and medication.

## **5.8 Power calculation**

The outcome used for the power calculation was the duration of hospital admissions. The aim of the study was to reduce this outcome by 30%, based on what had been achieved by earlier studies (e.g. Rich et al, 1995). Using 1999 data from the study hospital, the mean duration of hospital stay for patients with a primary diagnosis of heart failure was 13.3 days, median 9.6 days, SD11.3 days. To detect a 30% reduction in duration of hospital stay, with 80% power,  $\alpha = 0.05$ , required a total sample size of 198.

## **5.9 Measures**

The study measures were chosen on the following basis:

- To demonstrate that the intervention and control groups were similar in demographic background, disease severity and the medical treatment they received.
- To examine the effect of the intervention on mediator or process variables
- To examine the effect of the intervention on outcome variables
- To examine the role of potential moderator variables on the intervention i.e. variables which may influence the strength of the effect of the intervention on the outcome variable. These could include demographic variables such as education level and disease variables such as disease severity or duration.

A simple model of the proposed causal relations in the intervention is shown in Figure 5.1. It is acknowledged that there will be other inter-relations between the variables that

are not shown in this model. Also, some variables may directly affect the outcome, irrespective of any influence they may have on the intervention but these direct relationships are not shown (for example, co-morbidity may have a direct effect on outcomes as well as having a potential moderating effect on the intervention). In addition, it is recognised that a variable such as mood may act as a mediator and may change as a result of the intervention, but because mood was not directly targeted in the intervention, it is shown only as an outcome variable in this model.

A summary of the data collected and assessment times are shown in Table 5.1. Patient questionnaires are shown in Appendix E.

### **5.9.1. Demographic characteristics**

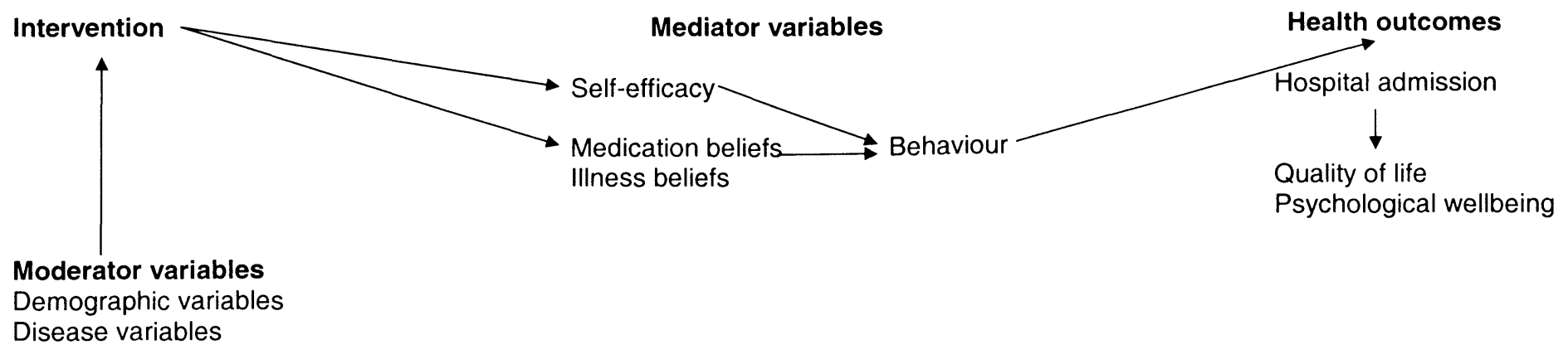
Data were collected on patients' age, gender, ethnicity, body mass index, marital status, education, employment status and living conditions.

### **5.9.2 Clinical variables**

#### **5.9.2.1 Medical history**

A cardiology research fellow recorded details of the patients' medical history. This included a history of cardiac and other co-morbid illness and also the history of their heart failure i.e. the aetiology of heart failure (whether ischaemic or non-ischaemic), whether heart failure was newly diagnosed on this admission to hospital, duration since diagnosis and history of hospital admissions.

Figure 5.1 Proposed causal model of the intervention



### **5.9.2.2 Co-morbidity**

The presence of co-morbid illness was considered likely to influence the study outcomes therefore participants were asked if they had been diagnosed with one or more of 5 major co-morbidities – cancer, stroke, arthritis, diabetes, asthma. Each illness was allocated a score of one and these were summed to provide a total score.

### **5.9.2.3 Echocardiographic evidence of left ventricular dysfunction**

Echocardiographic data were collected because they provide objective evidence of cardiac function. As such, they were important to ensure that the intervention and control groups did not differ significantly at baseline. Cardiac function is also a potential moderator variable as the severity of cardiac dysfunction could impact on a person's ability to adopt and maintain self-management behaviours. The global left ventricular function, as judged by the echocardiographer, and the regional wall motion score were recorded as indicators of the level of left ventricular dysfunction.

### **5.9.3 Physical examination**

Severity of heart failure symptoms, including breathlessness and oedema were assessed by the cardiologist who then classified patients' functional status according to New York Heart Association classification criteria (Dolgin, 1994). This is a descriptive classification of symptoms and disability based on patient report. Symptoms of heart failure on admission to hospital were also recorded from hospital notes as part of the baseline assessment.

### **5.9.4 Medication**

Information on medication prescription was recorded as an indicator of the extent to which the intervention and control groups received similar medical care. The type and daily dose of heart failure medications i.e. diuretics, ACE inhibitors and beta-blockers

were recorded at discharge from hospital for the baseline assessment and at 6-8 week and 12 month follow-ups. A list of other medications prescribed was also recorded.

#### **5.9.5 Hospital admission**

Both total admissions for worsening heart failure and those for any cause (including heart failure) were recorded. It is important to examine these separately as an intervention could be successful in reducing admissions for worsening heart failure but at the risk of causing other problems. For example, heart failure medication could reduce blood pressure to a level that results in a patient having a fall and requiring a hospital stay.

All readmissions of study patients to the Whittington Hospital were monitored and recorded. The cardiology research fellow (who was blind to group allocation) presented information on each admission to a panel of two cardiologists who were not involved in the study and were also blind to group allocation. The panel decided on the reason for the readmission i.e. whether for worsening heart failure or for other causes. The cardiology research fellow also visited the general practitioners of all patients and recorded details of admissions to other hospitals.

#### **5.9.6 Mortality**

The status of all study patients was recorded at 90 days and 12 months post discharge. If patients died during an admission to the Whittington hospital or the hospital had been advised about a death, the date of death was recorded from hospital records. Information on out of hospital deaths and deaths in other hospitals was obtained from patients' GPs. The patient consent form included consent to access information maintained by the NHS and the General Register Office so details of any deaths could be obtained from other sections of the NHS and/or the Office of National Statistics as necessary.

### **5.9.7 Time to first event**

The time in days to first event, either death or admission to hospital was also recorded. This outcome augments data on occurrence of an event in that it shows not only whether or not patients experienced an event during the follow-up period but also how long they survived without a readmission to hospital.

### **5.9.8 Questionnaire measures**

The questionnaires were chosen to measure factors that were likely to change as a result of the self-management intervention and also those that could influence response to the intervention.

#### **5.9.8.1 Quality of Life**

##### *5.9.8.1.1 Generic health related quality of life*

Generic health related quality of life was assessed with the Medical Outcomes Study Short Form 36 (SF-36) (Ware & Sherbourne, 1992). The SF-36 is a widely used measure of health-related quality of life. Eight subscales assess physical function, role limitation caused by physical function, pain, general health, energy/vitality, social function, role limitation caused by emotional difficulties and mental health. It also provides two composite scores for physical and mental quality of life. A U.K. version of the SF-36 with population norms is available (Jenkinson, Layte, Wright & Coulter 1996). To compare scores with populations norms, scores are transformed to a 0-100 scale on which the population mean is 50 and the standard deviation is 10. A higher score signifies better quality of life. The SF-36 has been validated for use with heart failure patients (Berry & McMurray 1999).

#### **5.9.8.1.2**      *Disease-specific quality of life*

Disease-specific quality of life was assessed with the Minnesota living with Heart Failure Questionnaire (MLHF) (Rector, Kubo & Cohn, 1987). The MLHF is a very widely used questionnaire for assessing heart failure related quality of life that has been validated and is user friendly (Berry & McMurray 1999). The MLHF is a 21 item questionnaire that asks how much heart failure had prevented the respondent living as they wanted to during the past month. Each item is scored 0 if it does not apply or from 1 – 5 on a scale signifying from 'very little' to 'very much'. The questionnaire provides a total score from 0 – 105 with a higher score signifying worse quality of life. The questionnaire also has a physical subscale comprising 8 of the items and an emotional subscale comprising 5 of the items.

#### **5.9.8.2      Psychological wellbeing**

Mood has been found to influence participation in self-management interventions (e.g. Shaw, Cronan & Christie, 1994) therefore it was considered an important factor to measure. Also, patients with heart failure are known to experience impaired mood (see section 2.4.2.3) and an intervention which enhanced patients' confidence in their ability to manage their illness might be expected to also improve mood (e.g. Lorig, Sobel, Stewart et al, 1999). Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983). This questionnaire was chosen because it was designed to assess anxiety and depression within a clinical population and therefore excludes somatic items that could lead to over-diagnosis of impaired mood in the physically ill. The HADS is a 14-item questionnaire that provides two separate scales for anxiety and depression. Each scale is scored from 0 – 21 with a higher score signifying greater anxiety or depression. A score of  $\geq 8$  indicates possible clinical depression/anxiety and a score of  $\geq 11$  indicates probable clinical depression/anxiety. Both the mean score and classification according to presence or absence of anxiety or depression were used in the analysis.

It was of interest to examine not only whether the intervention could reduce negative mood but also whether it could enhance feelings of positive mood. To assess mood in this way, the Positive and Negative Affect Scale (PANAS) was used (Watson, Clark, & Tellegen, 1988). The Positive and Negative Affect Schedule consists of two 10-item scales for positive affect and negative affect. Each scale is scored from 10–50 with higher scores indicating greater positive affect and greater negative effect. The PANAS has proven reliability and validity in a UK population (Crawford & Henry, 2004).

#### **5.9.8.3 Health behaviours**

Information on patients' smoking history, weekly alcohol consumption and weekly exercise were recorded at the baseline assessment and 6-8 week and 12 month follow-ups.

#### **5.9.8.4 Self-management behaviour**

At the time of the study development, a number of possible questionnaires to evaluate self-management behaviour were considered but no suitable questionnaire was identified. One questionnaire that had been published, developed by Riegel, Carlson & Glaser (2000), included questions about behaviours that were not part of the self-management intervention, for example, self-adjustment of diuretic medication, and therefore was considered inappropriate. Furthermore, it had undergone only preliminary reliability analyses and the developers of the scale did not advocate it for use for research purposes at that time. A measure by Bennett, Milgrom, Champion & Huster (1997) was concerned with beliefs about compliance rather than the practice of the relevant behaviours. Therefore a brief questionnaire was compiled for the study to assess the practice of self-management behaviours. This was based on the Revised Summary of Diabetes Self-Care Activities Scale (Toobert, Hampson & Glasgow, 2000).



The questionnaire asked respondents how many days out of the past seven they had performed each behaviour that formed part of the self-management intervention.

Physical activity was measured using a scale developed by Lorig, Stewart, Ritter et al 1996. This asks how much time was spent in 6 different physical activities over the course of the previous week, with answers on a 5-point ordinal scale from none, less than 30 minutes, 30-60 minutes, 1-3 hours and more than 3 hours. These are then converted to the number of minutes spent - 0, 15, 45, 120 and 180 respectively. A limitation of this conversion is that it could over- or under-estimate the actual time spent.

#### **5.9.8.5 Beliefs**

##### *5.9.8.5.1 Beliefs about medication*

The beliefs people hold about their medicines have been found to be associated with medication adherence (Horne & Weinman, 1999). Beliefs were assessed with the Beliefs about Medication Questionnaire (BMQ) (Horne, Weinman & Hankins, 1998). This questionnaire contains 10 items which items are scored on a 5-point Likert scale. It consists of two subscales that measure concerns about medication and beliefs about the necessity of taking medication.

##### *5.9.8.5.2 Self-efficacy beliefs – heart failure specific*

Self-efficacy is recognised as an important variable in self-management interventions. When the study was designed, there was no available questionnaire to assess heart failure self-efficacy beliefs. Ni et al (1999) had used only two items which were not behaviour specific and although the Kansas City Cardiomyopathy Questionnaire (Green, Porter, Bresnahan & Spertus, 2000) claims to measure this variable, the relevant items would appear to relate to knowledge rather than self-efficacy. Therefore a scale was developed for the study. Items were chosen that related to the behaviours

covered in the self-management intervention. The scale had seven items, measured on a 5-point Likert scale, a higher score indicating greater self-efficacy.

#### *5.9.8.5.3 Self-efficacy beliefs – general*

It is possible that people's beliefs about their general ability to cope with life's challenges may influence how they respond to a self-management intervention. These are known as general self-efficacy beliefs and were assessed with the Generalised Self-efficacy Scale (GSES) (Schwarzer 1993). This is a 10-item scale, scored on a 4-point scale from 'not at all true' to 'exactly true'. The scores of the 10 items are summed to provide a total score with higher scores indicating greater self-efficacy.

#### *5.9.8.5.4 Illness beliefs*

The beliefs people have about their illness have been shown to influence their health behaviour (e.g. Glasgow, Hampson, Strycker & Ruggiero, 1997) and therefore were assessed as part of the study. Illness beliefs were measured using the Illness perceptions Questionnaire (IPQ) (Weinman, Petrie, Moss-Morris & Horne, 1996) which is derived from the self-regulatory model of illness (Leventhal, Nerenz & Steele, 1984). The IPQ assesses beliefs about illness in 5 domains: (i) identity – the symptoms the person perceives to be related to the illness, (ii) cause – beliefs about what caused the illness (iii) timeline – perception of the likely time course, (iv) consequences – perception of the effect of the illness, (v) cure/control – beliefs about how amenable the illness is to cure and/or control. The identity sub-scale of the IPQ contains 12 core symptoms and these were supplemented with 7 other symptoms known to occur in heart failure. A total score is obtained by calculating the sum of the symptoms that respondents report experiencing. The timeline, consequences and cure/control subscales consist of 3, 7 and 6 items respectively, each scored on a 5-point Likert scale and summed to obtain a total score for the subscale. The analysis in this thesis concentrated on the dimensions of identity, consequences, cure/control and timeline.

#### **5.9.8.7 Patient satisfaction and value of the intervention**

Acceptability of the intervention to the patient was assessed in two ways. The Client Satisfaction Questionnaire (Attkisson & Zwick, 1982) was used to compare the intervention and control groups on levels of satisfaction with care. This is an 8-item scale, scored on a 4-point scale. A total score is obtained by calculating the sum of scores on the 8 items. Patients in the intervention groups also completed a questionnaire asking about how helpful they found the intervention. This was a 5-item measure, scored on a 5-point scale from 'not at all' to 'very much' which was designed for the study based on the components of the intervention. The scale also asked patients about their use of the intervention booklet, weight and medication charts.

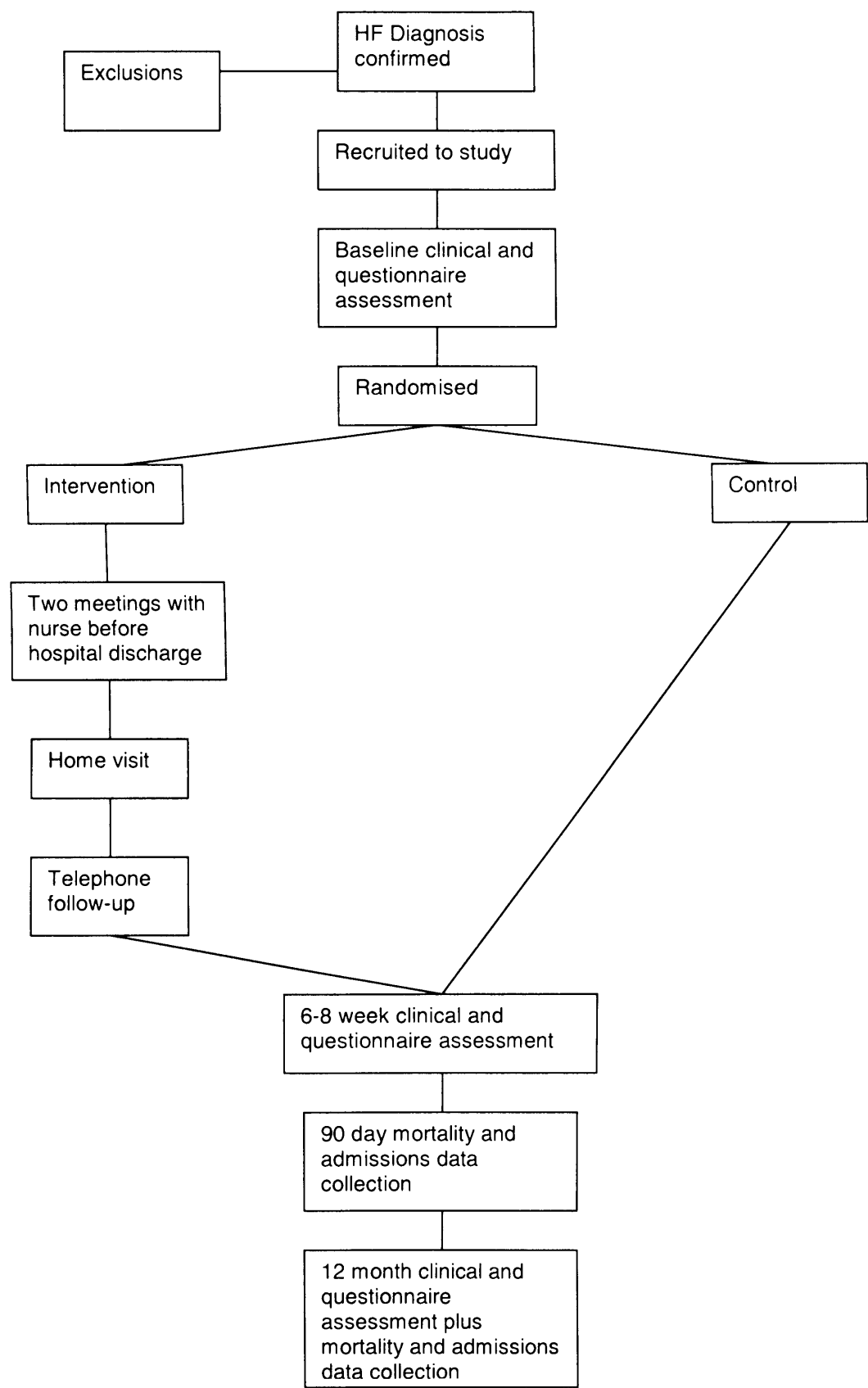
### **5.10 Procedures**

A flow-chart of the study procedures is shown in Figure 5.2

#### **5.10.1 Recruitment**

Potential study patients were identified through frequent checks of hospital admissions and inpatient echocardiograms and by physician referral to the heart failure team. All patients admitted with a possible diagnosis of heart failure were reviewed by a cardiology research fellow. Once clinically stable on optimal therapy and due to be discharged, the cardiology research fellow informed patients about the study and gave them the written information sheet (Appendix F). Patients were given at least an hour to read the information sheet, discuss it with their spouse or family members if they wished and consider whether they wanted to participate. The cardiology research fellow answered any questions that the patient and spouse or family members had about the study. Written consent was obtained.

Figure 5.2 Study procedures



### **5.10.2 Baseline assessment**

Before randomisation, the cardiology research fellow completed a clinical data collection form. This included both data which was collected from patient self-report e.g. current symptoms, and data collected from hospital records e.g. echocardiographic examination. All participants then completed baseline questionnaire assessments with the health psychology research fellow. Some clinical data were also recorded at the time of hospital discharge e.g. discharge medication.

### **5.10.3 Randomisation**

After completion of the baseline measures, patients were randomised to the intervention or standard care control group using pre-randomised sealed opaque envelopes.

## **5.10.4 Procedures for Intervention and Standard Care Control**

### **5.10.4.1 Standard Care Control Group**

Patients randomised to the control group received the hospital's standard medical care for heart failure as described in section 4.8. To ensure that intervention and control group patients received the same medical care, the cardiologists who provided follow-up care and conducted the clinical assessments were not advised of study group allocation. Patients in the control group had no contact with the heart failure nurse

### **5.10.4.2 Intervention group**

In addition to the care received by the standard care control group, patients in the intervention group were also seen by the heart failure nurse specialist. The self-management intervention described in the previous chapter was delivered in two sessions prior to discharge from hospital, plus a single home visit within one week of discharge followed by a telephone call one week later. Patients were encouraged to

contact the nurse if they identified signs of worsening heart failure. If patients in the intervention group were readmitted to hospital, the nurse visited them once before discharge. In addition to the self-management aspects of the intervention, at the home visit the nurse also reviewed the patient's clinical status and took any necessary action in accordance with a standard protocol. Any concerns were discussed with a cardiologist and additional clinic visits or admission to hospital could be arranged where necessary. The nurse's discussion of a patient with a cardiologist did not lead to 'unblinding' because the nurse also saw other patients who were not recruited to the study therefore the cardiologists would not have known whether or not the patient being discussed was a study patient.

### **5.10.5 Follow-up assessments**

#### **5.10.5.1 6-8 weeks post discharge**

Questionnaire and clinical data as shown in Table 5.1 were collected at 6-8 weeks post discharge. The assessment was organised to coincide with patients' routine out-patient cardiology visits. The questionnaire assessments were completed with the health psychology research fellow before patients had any investigative tests or were seen by the cardiologist.

#### **5.10.5.2 90 days post discharge**

Data on hospital admissions and mortality were collected at this time-point. The health psychology research fellow made frequent checks of hospital admissions and kept an on-going record of hospital admissions and deaths as they became known. The hospital's computer record of patient admissions was checked for all study patients to ensure that all events which occurred at the study hospital had been captured. The cardiology research fellow contacted the GPs of all study patients to obtain details of admissions to other hospitals and/or out of hospital deaths.

#### **5.10.5.3 12 months**

Hospitalisation, mortality, questionnaire and clinical data as shown in Table 5.1 were collected at 12 months post discharge. The questionnaire and clinical assessment was organised to coincide with patients' routine out-patient cardiology visits. The questionnaire assessments were completed with the health psychology research fellow before patients had any investigative tests or were seen by the cardiologist.

The method of collecting data on admissions and deaths that had been used to obtain the 90-day data was continued. The health psychology research fellow made frequent checks of hospital admissions and kept an on-going record of hospital admissions and deaths as they became known. The hospital's computer record of patient admissions was checked for all study patients to ensure that all events which occurred at the study hospital had been captured. The cardiology research fellow contacted the GPs of all study patients to obtain details of admissions to other hospitals and/or out of hospital deaths. In addition, all patients who attended their 12 month follow-up visit were asked if they had been admitted to any other hospitals in the previous year.

### **5.11 Statistical analysis**

Statistical analysis was performed using SPSS version 12.0.1 for Windows.

#### **5.11.1 Data cleaning**

The data were checked by examining the ranges of all variables to ensure that they fell within the ranges specified by the questionnaires or within usual ranges for that variable. Any that fell outside these ranges were checked and amended where necessary.

Where data were missing randomly, items were replaced with the group mean value of that item (Tabachnick & Fidell, 1996). If whole scales or subscales were missing, data on that (sub)scale for that participant were omitted from the analysis. The number of participants in each analysis is reported in the results section.

### **5.11.2 Distribution of variables**

Distribution of the variables was examined to check for normality of distribution. This was examined both visually, by plotting histograms, and statistically using the Kolmogorov-Smirnov test. When deciding whether to perform parametric or non-parametric tests, the advice of Tabachnick & Fidell (1996) was taken into account. They state that for two-tailed tests of analysis of variance (ANOVA) and analysis of covariance (ANCOVA), where the groups are fairly equal in size and there are no outliers, if there are at least 20 degrees of freedom for error, the test is considered robust to violations of normality.

Data collected on readmissions to hospital and mortality i.e. the number and duration of hospital admissions and the time between discharge from the index admission and either death or readmission (time to first event) were not expected to be normally distributed and appropriate non-parametric tests were used (see below).

#### **5.11.2.1 Outliers**

In analysis of variance analyses (ANOVA and ANCOVA) and logistic regression analyses, scores on independent variables were examined for outliers so that those greater than 3 standard deviations from the mean could be excluded.



### **5.11.3 Comparison of intervention and control groups on baseline characteristics**

The intervention and control groups were compared on baseline characteristics using Student's t-tests for continuous normally distributed data, chi-squared for categorical data and Mann-Whitney U tests for ordinal data and non-normally distributed continuous data.

### **5.11.4 Comparison of intervention and control group on study outcomes**

Chi-squared tests were used to compare the intervention and control groups on mortality and whether or not they had experienced a readmission to hospital. Readmissions for all causes and readmissions for worsening heart failure were distinguished. The number of readmissions to hospital and the number of days spent in hospital had a non-normal distribution and therefore Mann-Whitney U-tests were used to compare the intervention and control groups on these variables. The groups were also compared on rate of death, death or all-cause admission and death or heart failure readmission on a time to first event basis using Kaplan-Meier survival curves followed by the log-rank test which is used to test whether the survival distributions differ.

Differences between the groups at follow-up on other outcomes were examined by analysis of covariance (ANCOVA), with the baseline score entered as a covariate. ANCOVA, conducted at each follow-up, was chosen to examine intervention efficacy because it is a more sensitive test than repeated measures analysis of variance (ANOVA) (Tabachnick & Fidell, 1996). Separate ANCOVAs, as opposed to a single repeated measures ANOVA over all three time-points, also maximises participant numbers in the analysis. Post-hoc Bonferroni adjusted repeated measures ANOVAs were then performed to examine differences between baseline and follow-up within each group. While ANCOVAs are appropriate for examining group differences at each

time-point they do not show maintenance of change between follow-up assessments therefore Bonferroni repeated measures ANOVAs were also performed. These show time, group and interaction effects over the three assessment periods.

#### **5.11.5 Prediction of study outcomes**

To examine predictors of the occurrence of death or hospital admission and possible mediators of intervention outcomes, logistic regressions were performed. Logistic regression analyses the probability of a person having a particular outcome, given the pattern of their responses to the predictor variables. This statistical analysis does not require the predictors to be normally distributed, linearly related or of equal variance within each group, and the predictors can be continuous, discrete or dichotomous (Tabachnick & Fidell 1996). A minimum ratio of 10 cases per independent variable is recommended for logistic regression (Harrell, Lee, Califf et al 1984) where 'cases' refers to the number of observations of the less frequently occurring outcome.

To identify which independent variables were likely to be the best predictors, preliminary univariate analyses were performed and those variables that were significantly related to the outcome variable were entered into the regressions. The univariate analysis involved performing logistic regression analyses but entering only a single independent variable. A level of  $p \leq .05$  was used as a criterion for entry into the multivariate regression however, if the number of statistically significant independent variables identified using this entry criterion was too large to allow the recommended ratio of 10 cases per independent variable, the maximum recommended number of independent variables was chosen based on the highest Wald statistic values. The independent variables were entered into the regression in blocks in the following order: 1.study group, 2.demographic variables, 3. co-morbid illnesses, 4. echocardiographic

variables, 5. symptoms, 6. patients' beliefs about their illness, medication and self-efficacy, self-management behaviour, 7. mood.

To examine whether changes in self-efficacy and beliefs mediated any effect of the intervention on behaviour, the methods for mediator analysis recommended by Baron and Kenny (1986), using a series of regression analyses, were followed. For a mediator effect to arise, a) the independent variable must have a significant effect on the proposed mediator variable, b) the independent variable must have a significant effect on the dependent variable, and c) when the mediator and independent variable are both entered into the regression, the proposed mediator variable must have a significant effect on the dependent variable. For a mediator effect to be found, the effect of the independent variable on the dependent variable must be less in c) than in b).

This analysis was also undertaken to examine whether any effect of the intervention on the primary outcomes were mediated by behaviour.

To examine whether any variables moderated the effect of the intervention, a number of sub-group analyses were performed. The subgroups were selected on the basis of factors that had been found in the literature to have an impact on self-management in heart failure (this is dealt with in greater detail in section 10.4). An alternative approach would have been to test for all possible moderator variables however it was considered that this would involve too many statistical tests, increasing the risk of making a Type I error.

**Table 5.1. Assessment measures and times**

<b>Assessments</b>	<b>Baseline</b>	<b>6-8 weeks</b>	<b>90 days</b>	<b>12 months</b>
<b>Demographic variables</b> Age, sex, marital status, living conditions, ethnicity, education, height, weight, employment status	√			
<b>Disease variables</b> Aetiology of Heart failure, Previous cardiac history , Co-morbidity	√			
Symptoms and Signs of Heart Failure, NYHA	√	√		√
<b>Investigations</b> Echocardiogram, Chest x-ray,	√			
12 Lead ECG, Haematology, Biochemistry	√	√		√
<b>Medication</b> Type and daily dose	√	√		√
<b>Health Behaviours</b> Smoking, Exercise, Alcohol	√	√		√
<b>Self-management behaviours</b> Adherence to medication, self-monitoring and diet		√		√
<b>Resource utilisation</b> Number of hospitalisations for HF and for all causes Number of days hospitalised for HF and for all causes Number of nurse contacts (intervention group only )			√ √	√ √ √
<b>Mortality</b> Death from any cause			√	√
<b>Psychological well-being</b> <b>Mood</b> Anxiety – Hospital Anxiety and Depression Scale (HADS), Depression – HADS, Positive and Negative Affect Scale (PANAS)	√	√		√
<b>Quality of Life</b> Generic Health-related Quality of Life – SF-36 Disease specific – Minnesota Living with Heart Failure Questionnaire	√	√		√
<b>Process variables</b> Self-efficacy - general - HF specific Illness Perceptions – IPQ Beliefs about Medication Questionnaire	√ √ √ √	√ √ √ √		√ √ √ √
<b>Patient satisfaction</b> Client Satisfaction Questionnaire		√		√

## CHAPTER 6

### RESULTS – BASELINE CHARACTERISTICS

#### 6.1 Sample characteristics

Four hundred and sixty-seven patients with a diagnosis of heart failure who survived the index admission were identified, of which 263 (56%) were excluded (Figure 6.1). Of the 204 eligible patients, 38 (19%) refused participation and one hundred and sixty-six patients were recruited to the study. Eighty-five patients were randomised to the intervention group and 81 to the control group but after randomisation, the diagnosis of one control group patient was revised, rendering her ineligible for the study. The patient was treated as a protocol violation and her data were excluded from all analyses, leaving 80 patients in the control group.

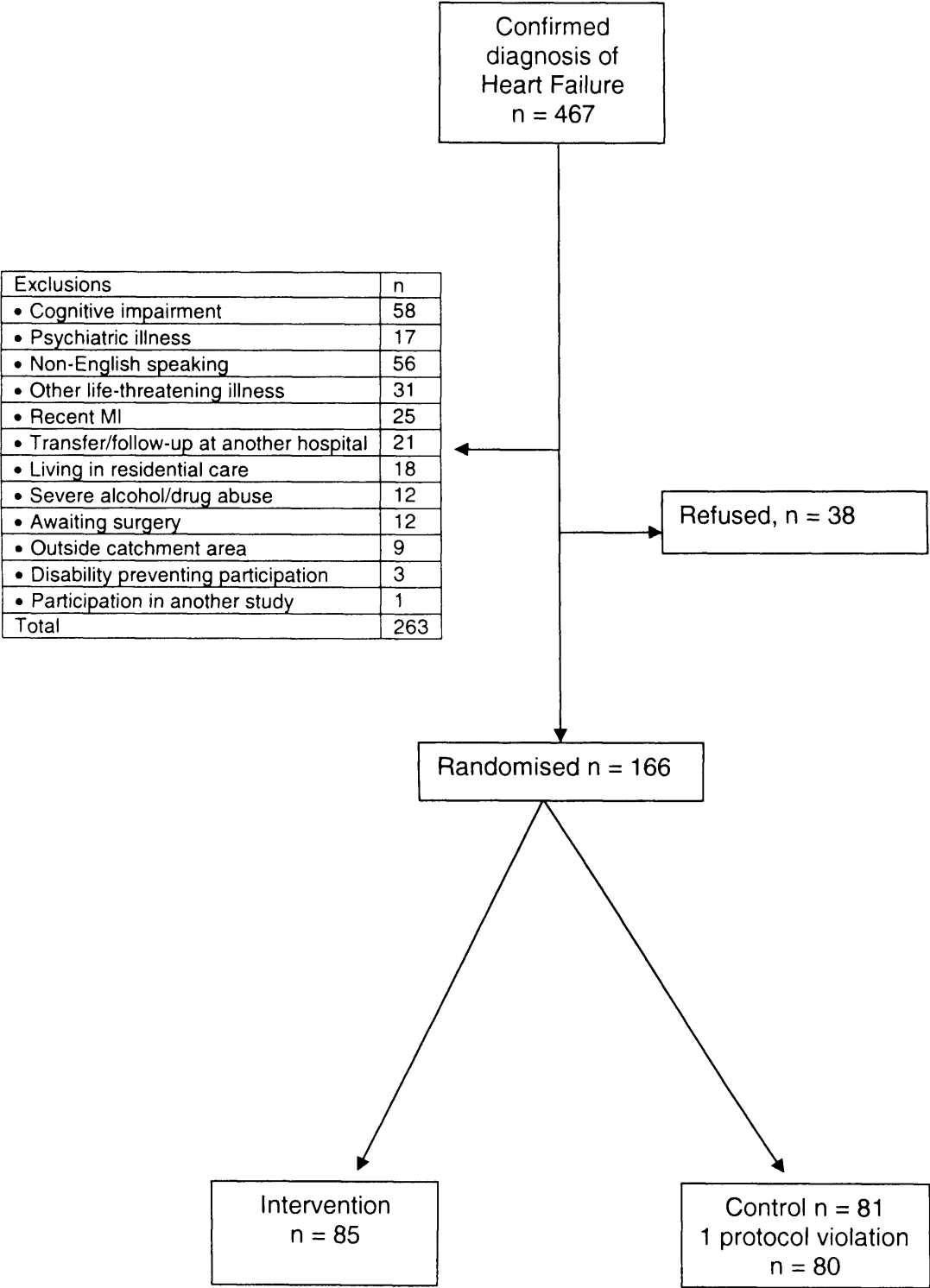
##### 6.1.1 Exclusions

Two hundred and sixty-three patients were ineligible for the study. The main reasons for exclusion were cognitive impairment (n = 58, 22%) and non-English speaking (n = 56, 21%).

##### 6.1.2 Demographic characteristics

The characteristics of the sample are shown in Table 6.1. The intervention and control groups did not differ significantly on any demographic variable. The study sample was not different from the general heart failure population in terms of age and gender, with a median age of 74, and almost 60% male. Education level was low with most having left school aged 14; two-thirds of patients had no formal qualifications. Nearly 60% of patients were living in social housing, an indication of the low socio-economic status of the study sample, which reflects the hospital catchment area.

Figure 6.1 Recruitment



**Table 6.1. Demographic characteristics**

<b>Variable</b>	<b>Total n = 165</b>	<b>Intervention n = 85</b>	<b>Control n = 80</b>	<b>Statistical significance</b>
<b>Age, median (range)</b>	74 (21-94)	74 (31-94)	75.5(21-93)	Mann-Whitney U = 3170.5, z= -.749, p = .45
<b>Male, n (%)</b>	96 (58.2)	50 (58.8)	46 (57.5)	$\chi^2$ (df=1) = .03, p = .86
<b>Ethnicity, n (%)</b>				$\chi^2$ (df=4) = 1.800, p = .77
<i>Afro-Caribbean</i>	16 (9.7)	7 (8.2)	9 (11.3)	
<i>Asian</i>	5 (3.0)	3 (3.6)	2 (2.5)	
<i>White British/Irish</i>	120 (72.7)	63 (74.1)	57 (71.3)	
<i>White other</i>	20 (12.1)	9 (10.6)	11 (13.8)	
<i>Other</i>	4 (2.4)	3 (3.5)	1 (1.3)	
<b>Marital status, n (%)</b>				$\chi^2$ (df=1) = .717, p = .40
<i>Married/Cohabiting</i>	59 (35.8)	33 (38.8)	26 (32.6)	
<i>Single/Divorced/Widowed</i>	106 (64.2)	52 (61.2)	54 (67.5)	
<b>Living, n (%)</b>				$\chi^2$ (df=2) = 1.112, p = .57
<i>Alone</i>	77 (46.7)	43 (50.6)	34 (42.5)	
<i>With others</i>	76 (46.1)	36 (42.4)	40 (50.0)	
<i>Sheltered accommodation</i>	12 (7.3)	6 (7.1)	6 (7.5)	
<b>Housing, n (%)</b>				$\chi^2$ (df=2) = 2.104, p = .35
<i>Owner occupier</i>	49 (29.7)	21 (24.7)	28 (35.0)	
<i>Social housing</i>	92 (55.8)	51 (60.0)	41 (51.3)	
<i>Other/unknown</i>	24 (14.5)	13 (15.3)	11 (13.8)	
<b>Years in full-time education, median (range)</b>	10 (0 – 22)	9 (0 – 19)	10 (4 – 22)	Mann-Whitney U = 2722, z = -1.661, p = .10

### **6.1.3 Clinical variables**

The clinical characteristics of the sample are shown in Table 6.2 and comorbid illnesses in Table 6.3. There were no significant differences between the intervention and control groups on any of these variables. The majority of patients had moderate or severe heart failure as evidenced by echocardiogram. Existence of comorbid illness was common, with 70.4% of the sample having at least one other significant comorbidity. The most frequently occurring were arthritis and diabetes, reported by 44.7% and 27.7% of patients respectively.

Almost all patients had been started on diuretics (97.6%) and ACE inhibitors (94.5%) prior to discharge indicating that the hospital's heart failure guidelines were being successfully implemented and optimised medical therapy applied in most cases. Pharmacological treatment did not differ significantly between intervention and control group patients.



**Table 6.2. Clinical variables at baseline**

Variable	Total n = 165	Intervention n = 85	Control n = 80	Statistical significance
<b>Heart Failure history</b>				
<i>HF = primary admitting diagnosis, n (%)</i>	142 (86.1)	76 (89.4)	66 (82.5)	$\chi^2$ (1df) = 1.641, p = .20
<i>New HF, n (%)</i>	90 (54.5)	43 (50.6)	47 (58.8)	$\chi^2$ (1df) = 1.107, p = .29
<i>Days in hospital on index admission, median (range)</i>	16 (4-116)	16 (5-116)	15.5 (4-86)	Mann Whitney U = 3100, z = -.979, p = .33
<b>NYHA class at recruitment to study, n (%)</b>				
<i>I</i>	13 (7.9)	7 (8.2)	6 (7.5)	Mann Whitney U = 3306.5, z = -.369, p = .71
<i>II</i>	111 (67.3)	58 (68.2)	53 (66.3)	
<i>III</i>	40 (24.2)	19 (22.4)	21 (26.3)	
<i>IV</i>	1 (0.6)	1 (1.2)	0 (0.0)	
<b>Echocardiogram -</b> Left ventricular subjective global function, n (%)				
<i>Unclassifiable</i>	14 (8.5)	8 (9.4)	6 (7.5)	$\chi^2$ (df=3) = 1.643, p = .65
<i>Mild</i>	29 (17.6)	14 (16.5)	15 (18.8)	
<i>Moderate</i>	55 (33.3)	25 (29.4)	30 (37.5)	
<i>Severe</i>	67 (40.6)	38 (44.7)	29 (36.3)	
<b>Medication at discharge from hospital (n= 164)</b> n (%) prescribed medication				
<i>Diuretics</i>	160 (97.6)	82 (97.6)	78 (97.5)	$\chi^2$ (df=1) = .002, p = .96
<i>ACE/ATII</i>	155 (94.5)	80 (95.2)	75 (93.8)	$\chi^2$ (df=1) = .175, p = .68
<i>B-blockers</i>	70 (42.7)	34 (40.5)	36 (45.0)	$\chi^2$ (df=1) = .343, p = .56
<i>Spironolactone</i>	106 (64.6)	58 (70.0)	47 (58.8)	$\chi^2$ (df=1) = 2.366, p = .12

**Table 6.3. Self-reported co-morbid illness**

<b>Illness</b> (data for n=159) n (%)	<b>Total</b> n = 159	<b>Intervention</b> n = 82	<b>Control</b> n = 77	<b>Statistical significance</b>
Diabetes mellitus	44 (27.7)	25 (30.5)	19 (24.7)	$X^2$ (df=1) = .670, p = .41
Cancer	12 (7.5)	6 (7.3)	6 (7.8)	$X^2$ (df=1) = .013, p = .91
COPD/Asthma	31 (19.5)	16 (19.5)	15 (19.5)	$X^2$ (df=1) = .000, p = 1.00
Stroke	21 (13.2)	11 (13.4)	10 (13.0)	$X^2$ (df=1) = .006, p = .94
Arthritis	71 (44.7)	32 (39.0)	39 (50.6)	$X^2$ (df=1) = 2.171, p = .14

**Table 6.4 Quality of life**

<b>Variable</b>	<b>Total</b>	<b>Intervention</b>	<b>Control</b>	<b>t</b>	<b>p</b>
<b>Generic Health-related Quality of Life (SF-36)<sup>1</sup></b>	n = 164	n = 85	n = 79	df=162	
<b>Composite Scores</b>					
<i>Physical, mean (S.D.)</i>	29.3 (11.7)	28.3 (10.5)	30.4 (12.8)	-1.139	.26
<i>Mental, mean (S.D.)</i>	44.3 (12.4)	43.9 (13.3)	44.7 (11.4)	-.437	.66
<b>Subscales</b>					
<i>Physical Function</i>	43.7 (28.9)	40.6 (27.2)	46.9 (30.5)	-1.385	.17
<i>Role Physical</i>	25.9 (34.2)	23.5 (32.6)	28.4 (36.0)	-.920	.36
<i>Pain</i>	65.2 (34.3)	63.7 (34.4)	66.8 (34.3)	-.587	.56
<i>General Health</i>	48.8 (19.8)	48.6 (20.6)	49.1 (19.0)	-.189	.85
<i>Vitality</i>	38.7 (23.7)	35.8 (23.4)	41.7 (23.7)	-1.600	.11
<i>Social Function</i>	57.8 (31.2)	56.5 (31.2)	59.2 (31.4)	-.560	.58
<i>Role Emotional</i>	40.8 (42.2)	41.2 (43.5)	40.4 (41.0)	.115	.91
<i>Mental Health</i>	67.3 (23.6)	65.6 (25.0)	69.0 (22.0)	-.912	.36
<b>Disease-specific Quality of Life (MLHF)</b>	n = 165	n = 85	n = 80	df=163	
<i>Total score, mean (SD)<sup>2</sup></i>	44.9 (22.5)	45.3 (22.7)	44.5 (22.4)	.212	.83
<i>Physical subscale<sup>3</sup></i>	23.6 (11.4)	24.1 (11.0)	23.2 (11.9)	.522	.60
<i>Emotional subscale<sup>4</sup></i>	7.6 (6.7)	7.5 (7.0)	7.8 (6.5)	-.301	.76

1. Scale 0 - 100, population norm 50, higher score = better quality of life

2. Scale 0 - 105, higher score = poorer quality of life

3. Scale 0 - 40, higher score = poorer physical quality of life

4. Scale 0 - 25, higher score = poorer emotional of life

#### **6.1.4 Quality of Life**

Baseline scores for Quality of Life are shown in Table 6.4. There were no significant differences between the intervention and control group on total scores or subscales of the generic and disease-specific measures.

##### **6.1.4.1 SF-36**

The mean physical composite score of the SF-36 was two standard deviations below the population mean, indicating impaired physical quality of life. The mean score on the mental composite score was within one standard deviation below the population mean, suggesting that in spite of having impaired physical quality of life, patients in this sample were able to maintain a reasonable mental quality of life. There was no statistically significant difference between the intervention and control groups on SF-36 subscales or composite scores (Table 6.4).

##### **6.1.4.2 Minnesota Living with Heart Failure Questionnaire**

The intervention and control groups did not differ significantly on the MLHFQ (Table 6.4).

#### **6.1.5 Mood**

Scores on the Hospital Anxiety and Depression Scale are shown in Table 6.5. There were no significant differences between the intervention and control groups on anxiety or depression. Comparison with normative data (Crawford, Henry, Crombie & Taylor, 2001) found that mean anxiety scores were very similar to the general adult UK population (a mean score of 6.53, compared with 6.14 in the general population) but mean depression scores were a little higher (5.54 in this study compared with 3.68 in the general population). The percentages reporting mild (a score of 8-10), moderate (a

score of 11-15) and severe anxiety (a score of 16 or over) in the current study were 19.5%, 17.1% and 3% respectively, compared with 20.6%, 10.0% and 2.6% respectively in the normative sample. The percentages reporting mild, moderate or severe depression were 19.5%, 11.6% and 0% respectively compared with 7.8%, 2.9% and 0.7% respectively in the normative sample (Crawford et al, 2001).

Comparison with normative data for the PANAS (Crawford & Henry 2004) found that the mean score on negative mood in this study was very similar to the normative sample (16.41 in the current study compared with 16.00 in the general population) however study patients reported lower levels of positive mood than the normative sample (a mean baseline score of 24 compared with the normative score of 32).

These findings indicate that although patients with severe psychiatric illness had been excluded, the psychological wellbeing of study participants was poorer than the general UK adult population.

**Table 6.5. Hospital Anxiety and Depression Scale**

Variable	Total	Intervention	Control	Statistical significance
N	164	84	80	
<b>Anxiety<sup>1</sup></b> mean (S.D.))	6.53 (4.37)	6.51 (4.41)	6..55 (4.35)	t (df=162) = -.056, p = .96
Mild (8-10), n (%)	32 (19.5)	17 (20.2)	15 (18.8)	X (df=3) = .381,, p = .94
Moderate (11-15), n (%)	28 (17.1)	15 (17.9)	13 (16.3)	
Severe (16-21), n (%)	5 (3.0)	2 (2.4)	3 (3.8)	
<b>Depression<sup>1</sup></b> mean (S.D.)	5.54 (3.72)	5.64 (3.54)	5.44 (3.92)	t (df=162) = .352, p = .73
Mild (8-10), n (%)	32 (19.5)	20 (23.8)	12 (15.0)	X (df=2) = 3.229, p = .20
Moderate (11-15), n (%)	19 (11.6)	7 (8.3)	12 (15.0)	
Severe (16-21), n (%)	0 (0.0)	0 (0.0)	0 (0.0)	

1. Scale 0 – 21, higher score = greater depression/anxiety

**Table 6.6. Positive and Negative Affect Scale**

<b>Variable</b>	<b>Total</b>	<b>Intervention</b>	<b>Control</b>	<b>Statistical significance</b>
<b>N</b>	163	83	80	
<b>Positive Affect<sup>1</sup></b> mean (S.D.)	24.74 (8.59)	23.72 (8.03)	25.79 (9.05)	$t(df=161) = -1.537, p = .13$
<b>Negative Affect<sup>1</sup></b> mean (S.D.)	16.41 (6.41)	15.70 (5.81)	17.14 (6.93)	$t(df=161) = -1.438, p = .15$

1. Scale 10 – 50, higher score = greater positive/negative affect

### 6.1.6 Process variables

Process variables are those through which the intervention may be expected to influence outcomes i.e. behaviours and cognitions.

#### 6.1.6.1 Health Behaviours

There was no difference in health behaviours between the intervention and control groups (Table 6.6). The majority were non-smokers and non-drinkers and sixty-five percent of patients were taking at least some exercise, although this could be as little as under thirty minutes per week.

**Table 6.7. Health behaviours**

Variable	Total	Intervention	Control	Statistical significance
<b>Smoking, n (%)</b>				$\chi^2$ (df=2) = 1.643, p = .44
<i>Current smoker</i>	18 (10.9)	7 (8.2)	11 (13.8)	
<i>Ex-smoker</i>	90 (54.5)	46 (54.1)	44 (55.0)	
<i>Never smoked</i>	57 (34.5)	32 (37.6)	25 (31.3)	
<b>Units of alcohol per week, n (%)</b>				$\chi^2$ (df=2) = 2.557, p = .28
<i>0</i>	93 (56.4)	53 (62.4)	40 (50.0)	
<i>1-21</i>	54 (32.7)	24 (28.2)	30 (37.5)	
<i>&gt;21</i>	18 (10.9)	8 (9.4)	10 (12.5)	
<b>Exercise per week<sup>1</sup>, median (range)</b>	82.5 (0-630)	45 (0-405)	120 (0-630)	Mann-Whitney U = 3042.5, z = -1.064, p = .29

1. Scale 0 – 1080, higher score = more time spent exercising

#### 6.1.6.2 Self-efficacy

Patients' self-efficacy beliefs are shown in Table 6.7. The intervention and control groups did not differ significantly in either general or heart failure specific self-efficacy beliefs.



**Table 6.8 General and disease specific self-efficacy**

Variable	Total	Intervention	Control	Statistical significance
<b>General self-efficacy<sup>1</sup></b> , mean (S.D.)	n = 159 27.7 (7.4)	n = 81 27.1 (7.5)	n = 78 28.3 (7.3)	t (df=157) = -.980 p = .33
<b>Heart failure self-efficacy<sup>2</sup></b> , mean (S.D.)	n = 160	n = 81	n = 79	
<i>Manage illness</i>	3.14 (1.12)	3.23 (1.21)	3.04 (1.02)	t (df=158) = 1.11 p = .27
<i>Monitor change</i>	3.08 (1.23)	3.21 (1.23)	2.95 (1.23)	t (df=158) = 1.34 p = .18
<i>Contact doctor/nurse</i>	3.41 (1.15)	3.47 (1.13)	3.35 (1.18)	t (df=158) = .63 p = .53
<i>Take medication</i>	3.92 (1.06)	3.83 (1.09)	4.03 (1.01)	t (df=158) = -1.19 p = .24
<i>Exercise</i>	2.56 (1.33)	2.59 (1.31)	2.52 (1.36)	t (df=158) = .35 p = .73
<i>Low salt diet</i>	3.23 (1.27)	3.33 (1.29)	3.13 (1.24)	t (df=158) = 1.03 p = .31
<i>Fluid intake</i>	3.46 (1.19)	3.62 (1.03)	3.29 (1.32)	t (df=158) = 1.74 p = .08

1. Scale 10 – 40, higher score = greater self-efficacy

2. Scale 1 – 5, higher score = greater self-efficacy

#### **6.1.6.3 Illness beliefs**

Scores on the Illness Perceptions Questionnaire are shown in Table 6.8.

The intervention and control groups did not differ significantly in the number of symptoms they attributed to heart failure with both reporting a mean of 9 symptoms. There was considerable variability in the beliefs of patients in the study about the timeline, consequences and controllability of their heart failure. There were no statistically significant differences between the intervention and control groups in these beliefs.

#### **6.1.6.4 Beliefs about medication**

Table 6.9 shows patients' scores on the Beliefs about Medication questionnaire. These scores indicate that, in general, patients believed that their medication was necessary and did not have strong concerns about it. There were no significant differences between intervention and control groups in medication beliefs.

**Table 6.9. Illness beliefs, mean (S.D.)**

Variable	Total	Intervention	Control	Statistical significance
Consequences <sup>1</sup> , n = 157	3.2 (.70)	3.1 (.60)	3.2 (.79)	t (df=155) = -.479, p = .63
Cure/control <sup>2</sup> , n = 157	3.4 (.58)	3.4 (.52)	3.4 (.64)	t (df=155) = .000 p = 1.00
Timeline <sup>3</sup> , n = 157	3.3 (.97)	3.3 (.95)	3.4 (.99)	t (df=155) = -.438 p = .66
Identity <sup>4</sup> , n = 158	9.1 (4.66)	8.8 (4.61)	9.4 (4.71)	t (df=156) = -.751 p = .45

1. Scale 1-5, higher score = more serious perceived consequences

2. Scale 1-5, higher score = greater perceived control

3. Scale 1-5, higher score = longer perceived timeline

4. Scale 0-19, higher score = more symptoms attributed to heart failure

**Table 6.10 Beliefs about medication**

Variable	Total	Intervention	Control	Statistical significance
Concerns <sup>1</sup> , n = 161	2.59 (.87)	2.60 (.88)	2.58 (.90)	t, (df=159) = .179, p = .86
Necessity <sup>2</sup> , n = 161	4.18 (.65)	4.14 (.65)	4.23 (.65)	t (df=159) = -.859, p = .39

1. 5-item Scale 1 – 5 , higher score = more concerned about taking medication

2. 5-item Scale 1 – 5 , higher score = stronger belief in the necessity of medication

## **6.2 Comparison of the study sample with other intervention studies.**

### **6.2.1 Participation rate**

Fifty-six percent of patients with confirmed heart failure were ineligible for the study. Of those who were eligible, 19% refused participation. It is difficult to compare these figures with other intervention studies as many studies have not reported these data while other studies report these data in different ways. For example, some studies include the number of patients who were screened for heart failure rather than those with a confirmed diagnosis, others report only the percentage of eligible patients who participated. However, similar participation rates are not uncommon. For example, Koelling, Johnson, Cody & Aaronson (2005) used very similar exclusion criteria and excluded 58% of patients, although their refusal rate of 11% was somewhat lower than the current study. McDonald, Ledwidge, Cahill et al (2001) excluded 43% of patients however it should be noted that in that study, which was conducted in Dublin, only 1 patient had to be excluded because of inability to speak English. The refusal rate of 21% was slightly higher than in the current study.

### **6.2.2 Demographic characteristics**

In terms of demographic make-up, the study sample is similar to other intervention studies. Although some intervention studies have recruited younger heart failure patients, a large proportion are comprised of populations with a mean age of over 70 years. Other intervention studies have typically recruited between 50-70% males so the current study is also comparable on this variable. Information on socio-economic status is rarely reported in studies of heart failure interventions making comparison with other studies difficult on this factor but given the low socio-economic status of the study sample it is likely that many other studies comprise less socially disadvantaged populations. In common with most other heart failure intervention studies, the majority

of participants were of white ethnicity, however, 28 (17%) spoke English as a second language, a variable that is not reported in other studies.

### **6.2.3 Disease severity**

Many other intervention studies have also recruited patients who had been admitted to hospital for heart failure, with similar inclusion and exclusion criteria to the current study. Disease severity of the patient population in this study is therefore likely to be broadly similar to that of other studies.

### **6.2.4 Presence of comorbid illness**

Prevalence of diabetes in the study sample (27.7%) was broadly similar to other studies which report rates ranging from 14% to 59% but with most comprising less than 35% of patients with diabetes. Rates of chronic pulmonary disease in other intervention studies range from 9-35% and the percentage in the current study (19.5%) falls within this range. The percentage of patients who have had a stroke, a history of cancer or arthritis is rarely reported in other heart failure intervention studies so comparison is not possible. These are however important comorbidities which are likely to have an impact on outcomes.

### **6.2.5 Quality of life**

The scores on the SF-36, generic health-related quality of life measure were similar to those found in other heart failure studies. In a sample of heart failure patients recruited to a trial of a hospital-to-home transition programme, Harrison, Browne, Roberts et al (2002) obtained baseline scores on the physical composite score of 28.63 in the intervention group and 28.35 in the control group. Scores on the mental composite score were 50.49 and 49.81 respectively. Jerant, Azari & Nesbitt (2001) measured

quality of life in patients randomised to three models of hospital discharge care and obtained baseline physical composite scores of 30.5, 30.3 and 31.1 and mental composite scores of 41.9, 42.1 and 42.9. An observational study which recruited patients admitted for heart failure related emergency admissions also reported similar quality of life with mean physical and mental composite scores of 33.88 and 42.79 respectively (Rodriguez-Artalejo, Guallar-Castillon, Pascual et al 2005).

Scores on the Minnesota Living with Heart Failure Questionnaire were also similar to samples in other heart failure studies. For example, O'Loughlin, Ledwidge & McDonald (2005) reported mean scores for the total scale, physical subscale and emotional subscale of 49.3 ( $\pm 26.1$ ), 23.8 ( $\pm 12.4$ ) and 10.9 ( $\pm 7.6$ ) respectively in a sample of hospitalised heart failure patients who were recruited to a multidisciplinary management programme. This indicates marginally poorer emotional quality of life than in the current study but almost identical physical quality of life. Scores very similar to the current study were also obtained by Dunagan, Littenberg, Ewald et al (2005) in a group of hospitalised heart failure patients recruited to a telephone-based disease management intervention. They reported baseline physical and emotional subscale scores of 23.0 ( $\pm 11.3$ ) and 8.2 ( $\pm 7.3$ ) respectively in their control group and 23.6 ( $\pm 10.8$ ) and 7.5 ( $\pm 7.5$ ) respectively in their intervention group. Similar scores were obtained by Harrison et al (2002), who reported baseline scores for the intervention group on the total scale, physical subscale and emotional subscale were 44.82, 25.46 and 6.38 respectively and for the control group were 44.56, 25.45 and 6.98 respectively. The observational study by Rodriguez-Artalejo et al (2005) also reported similar quality of life with mean scores for the total scale, physical subscale and emotional scale of 48.23, 25.67 and 9.91 respectively.

In summary, when compared to other intervention studies, the population recruited to the current study were broadly similar in terms of age and gender, heart failure disease

severity, comorbidity and quality of life. Comparison with other studies of socioeconomic status was not possible but the current study sample is likely to be of lower socioeconomic status than those of other studies due to the hospital catchment area.

## **CHAPTER 7**

### **RESULTS - HOSPITAL READMISSION AND MORTALITY**

This chapter reports outcomes for readmission to hospital and mortality in the 90 days and 12 months following discharge from the index admission. Hospital admissions data are reported both as total admissions for any cause and as admissions due to worsening heart failure. Mortality data refer to death from any cause; heart failure is not recorded as the cause of death on death certificates therefore no attempt was made to differentiate between causes of death.

#### **7.1 Attrition**

Nine patients randomised to the intervention group did not complete the intervention i.e. they did not meet with the nurse for all planned intervention sessions. Of these nine patients, one was transferred to another hospital and three patients became unwell before the first part of the intervention in hospital could be completed, the remaining five completed the in-hospital part of the intervention but then dropped out of the study and did not have any contact with the nurse after discharge from hospital. Two patients randomised to the control group subsequently became unwell prior to discharge from hospital and were discharged to residential care. Analyses were performed on an intention-to-treat basis therefore these patients are included in the results for hospitalisation and mortality that follow. All patients in the study were traced, including those who dropped out of the intervention or who moved away, thus mortality and hospital admissions data were collected for the complete study sample at both 90 day and 12 month assessment times.



## **7.2 Clinical care**

This study was designed to evaluate the impact of a self-management intervention over and above the medical care given to both groups. It is therefore necessary to first check that both groups received the same levels of care to ensure that any differences in outcomes can be attributed to the intervention and not to other differences in clinical care. It is not possible to examine directly whether both groups received the same level of follow-up care, but the number of cardiology out-patient appointments and the percentage of patients prescribed heart failure medications can be used to provide two useful indicators.

There was no statistically significant difference between the groups in the number of cardiology out-patient visits in the 12 months following discharge from the index admission. The intervention group had a median of 3 visits (range 0-10) and the control group had a median of 2 visits (range 0-9), Mann-Whitney,  $Z (163df) = -1.012$ ,  $p = .31$ . There were no statistically significant differences between the groups in the percentage prescribed heart failure medications at each time point (Table 7.1). These findings therefore indicate that the amount of care and prescription of medication was similar in both groups.

**Table 7.1 Prescribed medication**

<b>Medication, n (%) of patients prescribed medication</b>					
	<b>Assessment time</b>	<b>Total n</b>	<b>Intervention n, (%)</b>	<b>Control n, (%)</b>	<b>Statistical significance</b>
Diuretics	Baseline	164	82 (97.6)	78 (97.5)	Fisher's Exact test p = 1.00
	6-8 wks	137	64 (94.1)	67 (97.1)	Fisher's Exact test p = .44
	12 mths	111	52 (88.1)	48 (92.3)	Fisher's Exact test p = .54
ACE/ATII	Baseline	164	80 (95.2)	75 (93.8)	Fisher's Exact test p = .74
	6-8 wks	135	59 (90.8)	58 (82.9)	$\chi^2$ (1df) = 1.83, p = .18
	12 mths	111	48 (81.4)	48 (92.3)	Fisher's Exact test p = .10
Beta-blockers	Baseline	164	34 (40.5)	36 (45.0)	$\chi^2$ (1df) = .34, p = .56
	6-8 wks	139	28 (40.6)	34 (48.6)	$\chi^2$ (1df) = .90, p = .34
	12 mths	111	31 (52.5)	31 (59.6)	$\chi^2$ (1df) = .56, p = .45
Spironolactone	Baseline	164	59 (70.2)	47 (58.8)	$\chi^2$ (1df) = 2.37, p = .12
	6-8 wks	140	41 (58.6)	37 (52.9)	$\chi^2$ (1df) = .46, p = .50
	12 mths	110	24 (41.4)	25 (48.1)	$\chi^2$ (1df) = .50, p = .48

### 7. 3 Ninety day outcomes (Tables 7.2, 7.3, 7.4)

The following sections report the number of patients who were readmitted to hospital, the total number of admissions they had and the total number of days they spent in hospital. Also reported are the number of deaths and the combined end-point of death or hospital readmission. Time to first event is reported for the number of days following discharge that patients remained alive and without readmission to hospital (event-free survival).

**Table 7.2. Unplanned readmissions for *any cause* within 90 days of discharge**

	<b>Total</b>	<b>Intervention</b>	<b>Control</b>	<b>Statistical significance</b>
n	165	85	80	
Number of patients readmitted at least once, n (%)	51 (30.9)	25 (29.1)	26 (32.5)	$\chi^2$ (df=1) = .184, p= 0.67
Total number of readmissions (number per patient)	66 (0.4)	33 (0.4)	33 (0.4)	Mann-Whitney U = 3320, z= -.321, p= 0.75
Days in hospital (number per patient)	983 (6.0)	492 (5.8)	491 (6.1)	Mann-Whitney U = 3342, z= -.231, p= 0.82

**Table 7.3. Unplanned readmissions for *heart failure* within 90 days of discharge**

	<b>Total</b>	<b>Intervention</b>	<b>Control</b>	<b>Statistical significance</b>
n	165	85	80	
Number of patients readmitted at least once for HF, n (%)	24 (14.6)	10 (11.8)	14 (17.5)	$\chi^2$ (df=1) =1.091, p = .30
Total number of readmissions for HF (number per patient)	30 (0.2)	12 (0.1)	18 (0.2)	Mann-Whitney U = 3199, z = -1.071, p=.28
Days in hospital for HF (number per patient)	512 (3.1)	225 (2.6)	287 (3.6)	Mann-Whitney U = 3209, z = -1.016, p=.31

### **7.3.1 Number of patients readmitted to hospital in the 90 days post discharge**

The intervention and control groups did not differ significantly in the percentage of patients readmitted to hospital in the 90 days following discharge from the index admission. A total of 51 patients, 25 (29%) in the intervention group and 26 (33%) in the control group, had at least one unplanned readmission to hospital for any cause,  $\chi^2$  (1df) = .184,  $p = .67$  (Table 7.2). Of these, a total of 24 patients, 10 (12%) in the intervention group and 14 (18%) in the control group, were readmitted at least once for heart failure,  $\chi^2$  (1df) = 1.091,  $p = .30$  (Table 7.3).

### **7.3.2 Number of hospital admissions in the 90 days post discharge**

The intervention and control groups did not differ significantly in the total number of hospital readmissions in the 90 days following discharge from the index admission. A total of 66 unplanned readmissions to hospital for any cause occurred during the 90 day period, 33 in each group,  $Z(163df) = -.321$ ,  $p = .75$  (Table 7.2). Of these, 30 admissions were for heart failure, 12 in the intervention group and 18 in the control group,  $Z(163df) = -1.071$ ,  $p = .28$  (Table 7.3).

### **7.3.3 Number of days spent in hospital in the 90 days post discharge**

The intervention and control groups did not differ significantly in the number of days spent in hospital in the 90 days following discharge from the index admission. A total of 983 days were spent in hospital owing to unplanned admission for any cause, 492 (5.8 per patient) in the intervention group and 491 (6.1 per patient) in the control group,  $Z(163df) = -.231$ ,  $p = .82$  (Table 7.2). Of these, 512 days were spent in hospital for heart failure, 225 (2.6 per patient) in the intervention group and 287 (3.6 per patient) in the control group,  $Z(163df) = -1.016$ ,  $p = .31$  (Table 7.3).

### 7.3.4. All cause mortality in the 90 days post discharge (Table 7.4)

Mortality did not differ significantly between the intervention and control groups in the 90 days following discharge from the index admission. A total of 14 patients died in the 90 days post discharge, 8 (9.4%) in the intervention group and 6 (7.5%) in the control group,  $\chi^2$  (1df) = .194,  $p$  = .66.

**Table 7.4. Combined outcome of death or readmission to hospital within 90 days of discharge**

	<b>Total</b>	<b>Intervention</b>	<b>Control</b>	<b>Statistical significance</b>
n	165	85	80	
Mortality, n (%)	14 (8.5)	8 (9.4)	6 (7.5)	$\chi^2$ (df=1) =.194, $p$ = .66
Death or <b>all-cause</b> readmission, n (%)	57 (34.6)	30 (35.3)	27 (33.8)	$\chi^2$ (df=1) =.043, $p$ = .84
Death or <b>heart failure</b> readmission, n (%)	33 (20.0)	17 (20.0)	16 (20.0)	$\chi^2$ (df=1) =.000, $p$ = 1.00

### 7.3.5 Combined end-point of death or readmission to hospital in the 90 days post discharge (Table 7.4)

The intervention and control groups did not differ significantly in the combined end-point of death or readmission to hospital in the 90 days following discharge from the index admission. Fifty-seven patients, 30 (35%) in the intervention group and 27 (34%) in the control group died or were readmitted to hospital,  $\chi^2$  (1df) = .043,  $p$  = .84. Event-free survival at 90 days for the study sample was therefore 65.4%. Of those who experienced an event, 33 died (of any cause) or were readmitted to hospital for heart failure, 17 (20%) in the intervention group and 16 (20%) in the control group,  $\chi^2$  (1df) = .000,  $p$  = 1.00.

### 7.3.6 Time to first event

Rates of death, death or readmission for any cause and death or readmission for heart failure were examined on a time to first event basis using the log rank test (Table 7.5). No statistically significant differences were found between the groups in time to death, time to first all-cause event (death from any cause or hospital readmission for any cause), or time to first heart failure event (death from any cause or hospital readmission for heart failure). Kaplan-Meier curves depicting event-free survival for these three outcomes at 90 days are shown in Figures 7.1, 7.2 and 7.3.

**Table 7.5. Time to first event within 90 days of hospital discharge**

Outcome	Log rank test
Time to death	Log rank (df=1) = .20, p = .65
Time to death or all-cause admission	Log rank (df=1) = .01, p = .90
Time to death or heart failure admission	Log rank (df=1) = .00, p = .99

Figure 7. 1 Time to first event – 90 day mortality

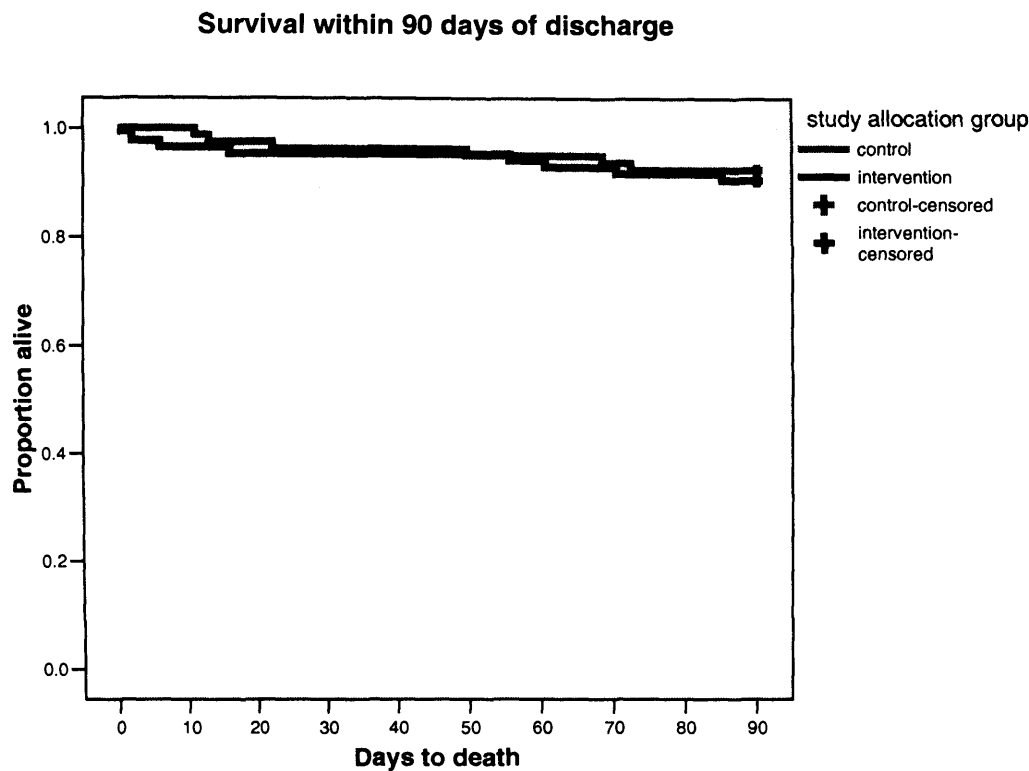


Figure 7.2 Time to first event – death or all cause admission within 90 days

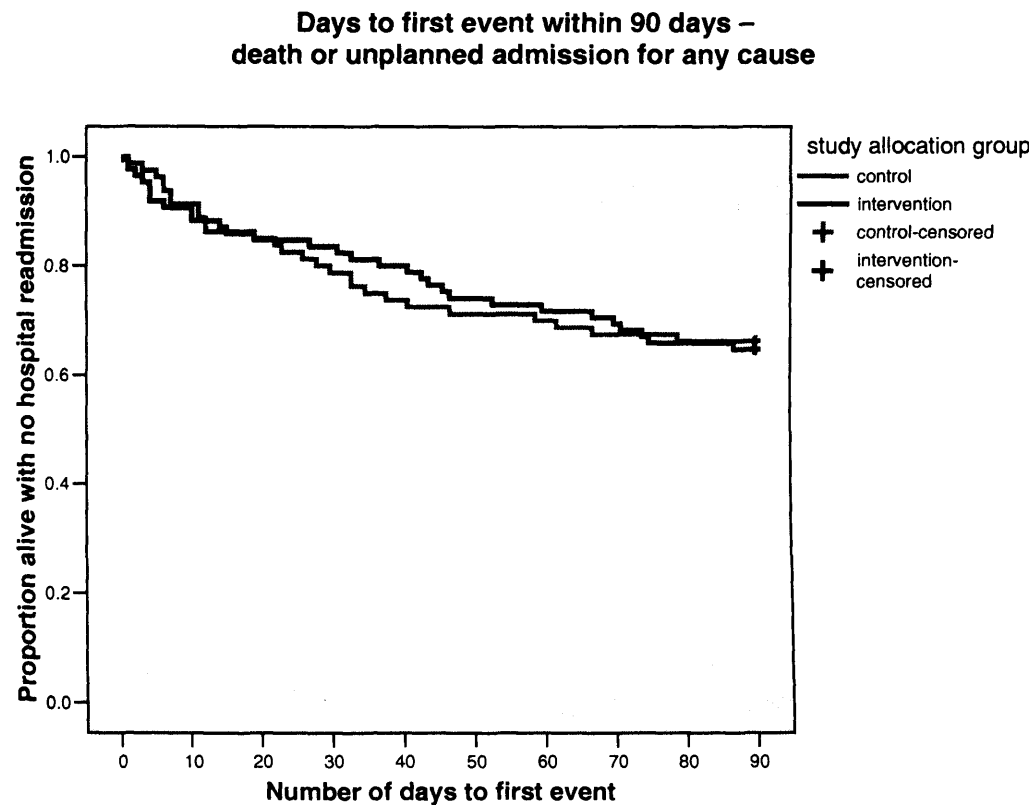
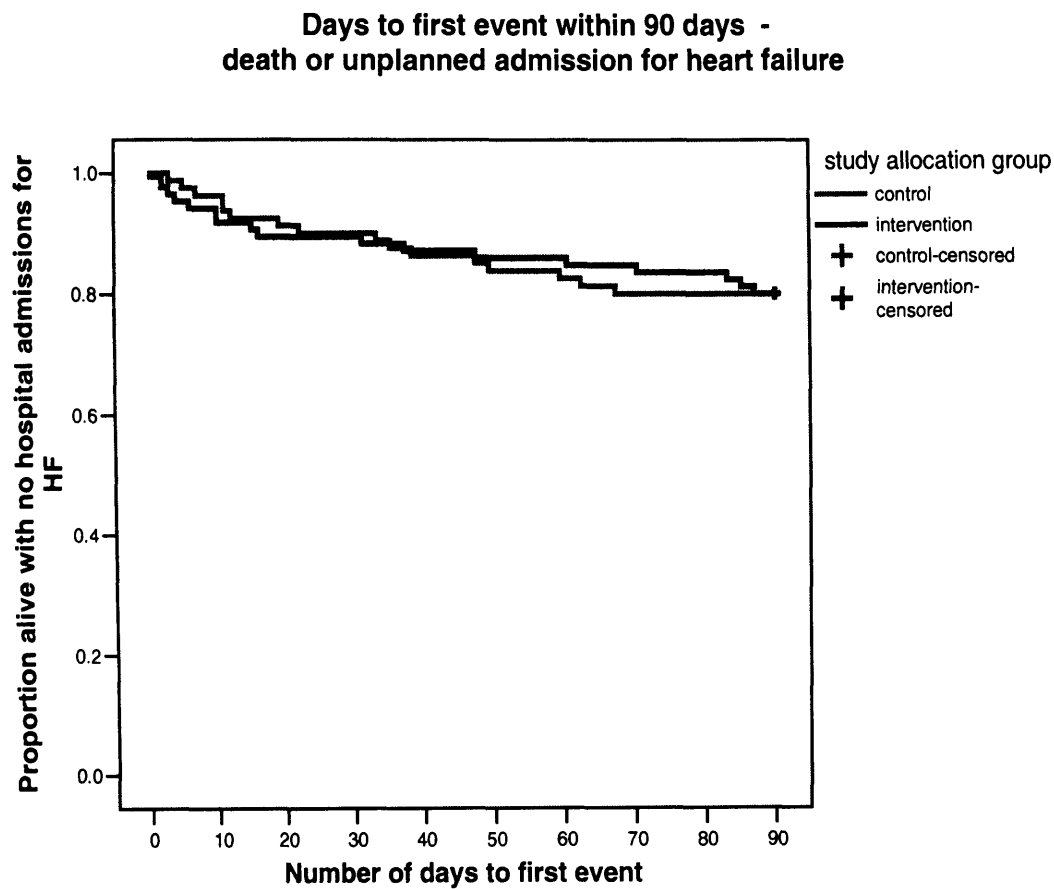


Figure 7.3 Time to first event – death or heart failure admission within 90 days





### **7.3.7 Summary of 90 day outcomes for hospitalisation and mortality**

In the 90 days following discharge from the index hospital admission, there were no statistically significant differences between the intervention and control group in the number or rate of deaths, the number of patients readmitted to hospital, the number or rate of admissions or the number of days spent in hospital, either for all causes or for heart failure.

#### 7.4 Twelve month outcomes (Tables 7.6, 7.7, 7.8)

The following sections report the number of patients who were readmitted to hospital, the total number of admissions they had and the total number of days they spent in hospital. Also reported are the number of deaths and the combined end-point of death or hospital readmission. Time to first event is reported for the number of days following discharge that patients remained alive and without readmission to hospital.

**Table 7.6. Unplanned readmissions for *any cause* within 12 months of discharge**

n	Total 165	Intervention 85	Control 80	Statistical significance
Number of patients readmitted at least once, n (%)	91 (55.2)	46 (54.1)	45 (56.3)	$\chi^2$ (df=1) = .076, p=.78
Total number of readmissions (number per patient)	191 (1.2)	105 (1.2)	86 (1.1)	Mann-Whitney U = 3390, z = -.035, p=.97
Days in hospital (number per patient)	3674 (22.3)	2224 (26.2)	1450 (18.1)	Mann-Whitney U=3353.5, z = -.159, p= .87

**Table 7.7. Unplanned readmissions for *heart failure* within 12 months of discharge**

n	Total 165	Intervention 85	Control 80	Statistical significance
Number of patients readmitted at least once for HF, n (%)	47 (28.5)	19 (22.4)	28 (35.0)	$\chi^2$ (df=1) = 3.236, p=.07
Total number of readmissions for HF (number per patient)	85 (0.5)	41 (0.5)	44 (0.6)	Mann-Whitney U=3002.5, z = -1.634, p=.10
Total number of days in hospital for HF (number per patient)	1544 (9.4)	858 (10.1)	686 (8.6)	Mann-Whitney U=3011.5, z = -1.591, p=.11

#### **7.4.1 Number of patients readmitted to hospital in the 12 months post discharge**

The intervention and control groups did not differ significantly in the percentage of patients admitted to hospital in the 12 months following discharge from the index admission. A total of 91 patients, 46 (54.1%) in the intervention group and 45 (56.3%) in the control group, had at least one unplanned readmission to hospital for any cause,  $\chi^2 (1df) = .076$ ,  $p = .78$ . Of these, a total of 47 patients, 19 (22.4%) in the intervention group and 28 (35%) in the control group, were readmitted at least once for heart failure,  $\chi^2 (1df) = 3.236$ ,  $p = .07$ .

#### **7.4.2 Number of hospital admissions in the 12 months post discharge**

The intervention and control groups did not differ significantly in the number of readmissions to hospital in the 12 months following discharge from the index admission. A total of 191 unplanned readmissions to hospital for any cause occurred, 105 (1.24 per patient) in the intervention group and 86 (1.08 per patient) in the control group,  $Z(163,df) = -.035$ ,  $p = .97$ . Of these, 85 admissions were for heart failure, 41 (0.48 per patient) in the intervention group and 44 (0.55 per patient) in the control group  $Z(163,df) = -1.634$ ,  $p = .10$ .

#### **7.4.3 Number of days spent in hospital in the 12 months post discharge**

The intervention and control groups did not differ significantly in the number of days spent in hospital in the 12 months following discharge from the index admission. A total of 3674 days were spent in hospital owing to unplanned admission for any cause, 2224 (26.2 per patient) in the intervention group and 1450 (18.1 per patient) in the control group  $Z (163,df) = -.159$ ,  $p = .87$ . Of these, 1544 days were spent in hospital for heart failure, 858 (10.1 per patient) in the intervention group and 686 (8.5 per patient) in the control group,  $Z(163,df) = -1.591$ ,  $p = .11$ .

#### 7.4.4 All cause mortality in the 12 months post discharge

Mortality in the 12 months post discharge did not differ significantly between the intervention and control groups. A total of 29 patients died, 13 (15.3%) in the intervention group and 16 (20.0%) in the control group,  $\chi^2$  (1df) = .630,  $p = .43$ .

**Table 7.8. Combined outcome of death or readmission to hospital within 12 months of discharge**

n	Total 165	Intervention 85	Control 80	Statistical significance
Mortality, n (%)	29 (17.6)	13 (15.3)	16 (20.0)	$\chi^2$ (df=1) = .630, $p = .43$
Death or all-cause admission, n (%)	100 (60.6)	53 (62.4)	47 (58.8)	$\chi^2$ (df=1) = .224, $p = .64$
Death or HF admission, n (%)	61 (37.0)	27 (31.8)	34 (42.5)	$\chi^2$ (df=1) = 2.038, $p = .15$

#### 7.4.5 Combined end-point of death or readmission to hospital in the 12 months post discharge

The intervention and control groups did not differ significantly in the combined end-point of death or readmission to hospital in the 12 months post discharge. One hundred patients, 53 (62.4%) in the intervention group and 47 (58.8%) in the control group died or were readmitted to hospital,  $\chi^2$  (1df) = .224,  $p = .64$ . Event-free survival at 12 months for the whole sample was therefore 39.4%. Of those who had an event, 61 died or were readmitted to hospital for heart failure, 27 (31.8%) in the intervention group and 34 (42.5%) in the control group,  $\chi^2$  (1df) = 2.038,  $p = .15$ .

#### 7.4.6 Time to first event

Rates of death, death or readmission for any cause and death or readmission for heart failure were examined on a time to first event basis using the log rank test (Table 7.9). No statistically significant differences were found between the groups in time to death,

time to first all-cause event (death from any cause or hospital readmission for any cause), or time to first heart failure event (death from any cause or hospital readmission for heart failure). Kaplan-Meier curves depicting event-free survival for these three outcomes at 12 months are shown in Figures 7.4, 7.5 and 7.6.

**Table 7.9. Time to first event within 12 months of hospital discharge**

Outcome	Log rank test
Time to death	Log rank (df=1) = .56, p= .45
Time to death or all-cause admission	Log rank (df=1) = .12, p= .73
Time to death or heart failure admission	Log rank (df=1) = 1.80, p= .18

Figure 7.4 Time to first event – 12 month mortality

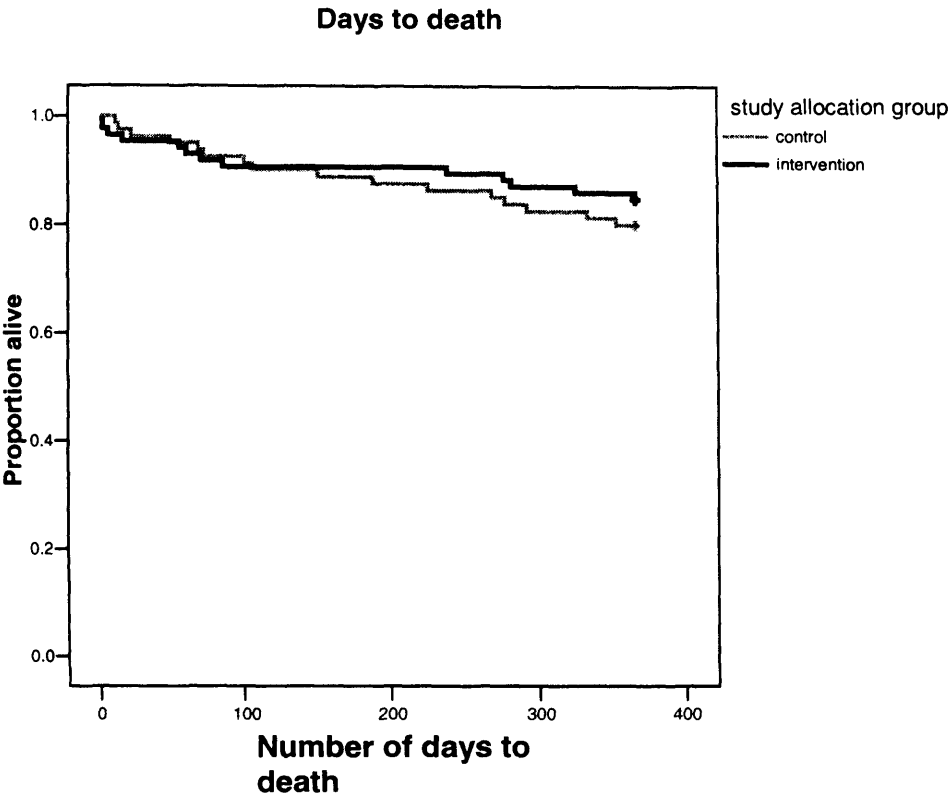
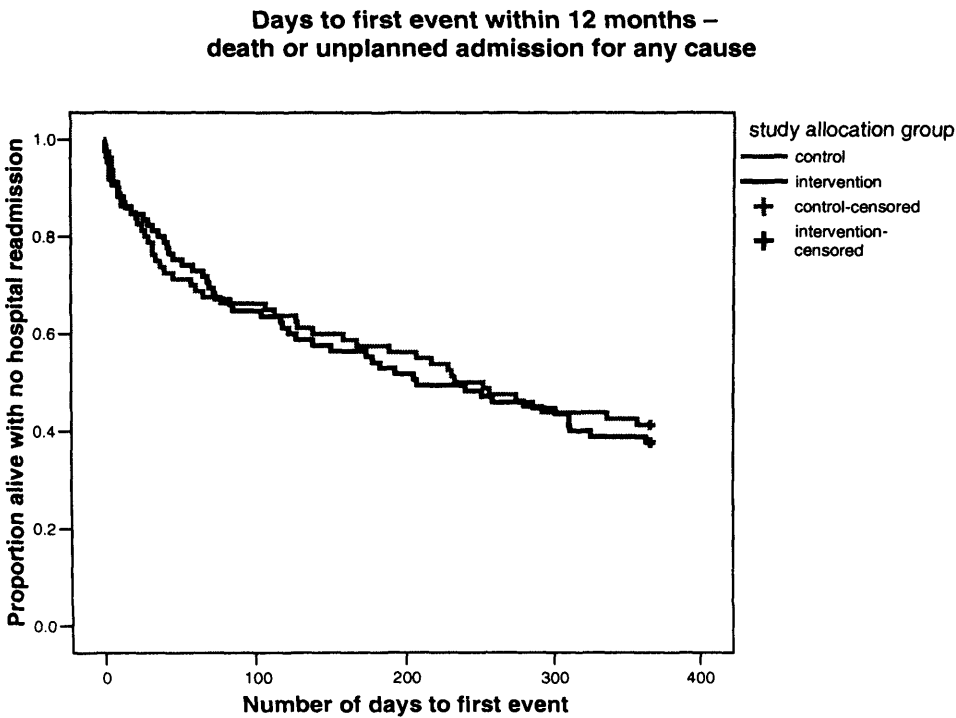
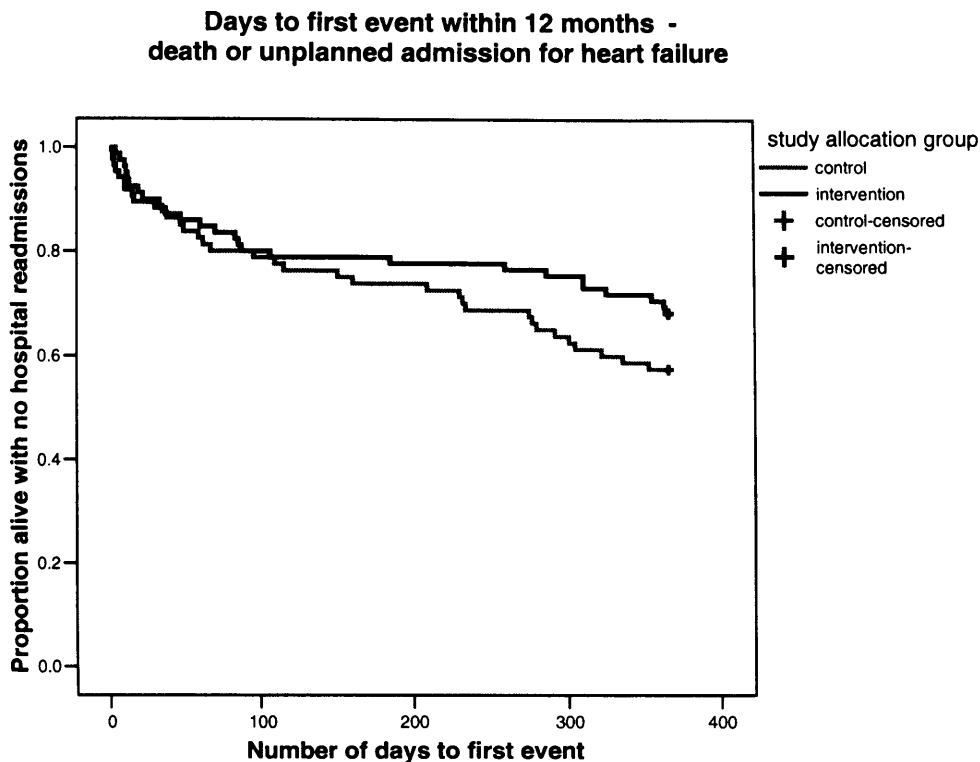


Figure 7.5 Time to first event – death or all cause admission within 12 months



**Figure 7.6 Time to first event – death or heart failure admission within 12 months**



#### **7.4.7 Summary of 12 month outcomes for hospitalisation and mortality**

In the 12 months following discharge from the index hospital admission, there were no statistically significant differences between the intervention and control group in the number or rate of deaths, the number of patients readmitted to hospital, the number or rate of admissions or the number of days spent in hospital either for all causes or for heart failure.

#### **7.5 Findings in participants who completed the study**

The results that have been reported in this chapter are based on intention-to-treat analysis. The reasons for using intention-to-treat analysis were outlined in chapter 5. However, it might be argued that evaluation of an intervention's efficacy should be based only on those who actually completed the intervention. Therefore the analysis

was repeated excluding those 9 patients in the intervention group and 2 patients in the control group who may be considered study dropouts (see section 7.1). The results in this analysis did not differ from the findings reported in the sections above.



## CHAPTER 8

### RESULTS - QUALITY OF LIFE AND MOOD

#### 8.1 Quality of Life

Quality of life was assessed with both a generic and a heart-failure-specific measure of health-related quality of life. Generic health-related quality of life was assessed with the SF-36 (Ware & Sherbourne, 1992; Jenkinson et al, 1996) which was completed by 164 patients at baseline and by 143 and 109 patients at 6-8 weeks and 12 months respectively. One hundred and six patients completed the assessment at all three time points. Disease specific quality of life was assessed with the Minnesota Living with Heart Failure Questionnaire (MLHF) (Rector et al, 1987). This was completed by all 165 patients at baseline and by 144 and 110 patients at 6-8 weeks and 12 months respectively. One hundred and nine patients completed the assessment at all three time points.

Examination of the distribution of the data showed that the physical and mental composite scores of the SF-36 were normally distributed at baseline and 6-8 weeks (Kolmogorov-Smirnov test,  $p \geq .05$ ). Neither were normally distributed at 12 months, however skewness and kurtosis fell within acceptable levels to meet parametric requirements of normality. The MLHF total score was normally distributed at baseline but not at the two follow-up assessments however skewness and kurtosis fell within acceptable levels.

Mean and S.D. scores on the 8 subscales of the SF-36 at each time point are shown in Table 8.1. Scores on all eight subscales were below the population norm of 50 at all three time-points. The intervention and control groups did not differ on these subscales

except on role emotional at 6-8 weeks at which time the intervention group reported better QoL on this subscale,  $t(df=141) = 2.02, p < .05$ .

Mean and S.D. scores on the physical composite score and mental composite score of the SF-36 and the total score of the MLHF for total completers at each time point are shown in Table 8.2. There were no significant differences in baseline scores on these scales between patients who completed assessments at all timepoints and those who did not.

Analyses of covariance (ANCOVA) were performed to compare the groups on the composite scores at 6-8 weeks and at 12 months, co-varying for baseline scores. Bonferroni adjusted repeated measures analysis of variance (ANOVAs) were then performed to examine change over time within each group. Results at 6-8 weeks are shown in Table 8.3 and results at 12 months are shown in Table 8.4.

There were no statistically significant differences between the groups or changes over time within the groups on the physical composite score of the SF-36 at 6-8 weeks or 12 months. Quality of life on the mental composite score of the SF-36 did not differ significantly between the groups at 6-8 weeks ( $F(1, 139) = 3.19, p = .08$ ) or 12 months ( $F(1, 105) = 3.76, p = .06$ ). There was however a significant improvement from baseline to 6-8 weeks in the intervention group ( $F(1, 71) = 9.67, p = .003$ ) but not the control group ( $F(1, 69) = .35, p = .56$ ). At the 12 month follow-up, scores on the mental composite score remained higher than at baseline in the intervention group ( $F(1, 55) = 16.10, p < .001$ ) but there was no change between baseline and 12 months in the control group ( $F(1, 51) = 2.49, p = .12$ ).

**Table 8.1 SF-36 Quality of life subscale scores at baseline, 6-8 weeks and 12 months**

		n	Intervention	Control	Between group differences
<b>Vitality</b>	Baseline	164	37.13 (11.89)	40.13 (12.05)	t (df=162) = -1.60, p = .11
	6-8 wks	144	42.64 (11.99)	42.73 (10.79)	t (df=142) = -.05, p = .96
	12 months	111	42.74 (11.47)	42.55 (13.73)	t (df=109) = .08, p = .94
<b>General Health</b>	Baseline	165	37.45 (10.35)	37.75 (9.56)	t (df=163) = -.19, p = .85
	6-8 weeks	144	36.57 (11.04)	36.57 (10.11)	t (df=142) = .00, p = 1.00
	12 months	110	35.76 (11.44)	37.23 (12.00)	t (df=108) = -.66, p = .51
<b>Mental Health</b>	Baseline	164	45.29 (14.51)	47.24 (12.78)	t (df=162) = -.91, p = .36
	6-8 weeks	144	49.07 (13.66)	48.58 (12.36)	t (df=142) = .22, p = .82
	12 months	111	49.22 (13.39)	48.50 (11.78)	t (df=109) = .30, p = .77
<b>Pain</b>	Baseline	165	41.78 (15.88)	43.23 (15.82)	t (df=163) = -.59, p = .56
	6-8 weeks	144	43.31 (14.76)	44.61 (14.80)	t (df=142) = -.53, p = .60
	12 months	111	42.09 (14.55)	43.64 (13.51)	t (df=109) = -.58, p = .56
<b>Physical Function</b>	Baseline	165	23.44 (15.13)	26.90 (16.98)	t (df=163) = -1.39, p = .17
	6-8 weeks	143	24.59 (15.30)	25.39 (16.76)	t (df=141) = -.30, p = .77
	12 months	111	23.86 (16.33)	27.61 (16.78)	t (df=109) = -1.19, p = .24
<b>Role Emotional</b>	Baseline	165	36.85 (13.71)	36.61 (12.90)	t (df=163) = .12, p = .91
	6-8 weeks	143	41.53 (12.31)	37.19 (13.39)	<b>t (df=141) = 2.02, p &lt; .05</b>
	12 months	110	47.32 (11.14)	43.13 (12.69)	t (df=108) = 1.84, p = .07
<b>Role Physical</b>	Baseline	165	29.19 (10.89)	30.83 (12.02)	t (df=163) = -.92, p = .36
	6-8 weeks	144	32.31 (10.95)	31.44 (11.11)	t (df=142) = .47, p = .64
	12 months	111	37.01 (12.54)	36.79 (13.52)	t (df=109) = .09, p = .93
<b>Social Function</b>	Baseline	164	33.89 (15.94)	35.29 (16.04)	t (df=162) = -.56, p = .58
	6-8 weeks	144	35.60 (17.01)	36.22 (14.92)	t (df=142) = -.23, p = .82
	12 months	111	38.10 (15.36)	35.74 (15.92)	t (109 df) = .80, p = .43

**Table 8.2. Quality of life scores at baseline, 6-8 weeks and 12 months, mean (S.D.)**

		n	Intervention	Control	Between group differences
<b>SF-36<sup>1</sup> Physical</b>	Baseline	164	28.33 (10.51)	30.41 (12.78)	t (162 df) = -1.14, p = .26
	6-8 wks	143	28.71 (12.00)	30.11 (12.09)	t (141 df) = -.70, p = .49
	12 mths	109	28.81 (13.89)	31.42 (13.49)	t (107 df) = -.99, p = .32
<b>SF-36<sup>1</sup> Mental</b>	Baseline	164	43.85 (13.31)	44.70 (11.43)	t (162 df) = -.44, p = .66
	6-8 weeks	143	48.56 (11.95)	46.52 (10.32)	t (141 df) = 1.09, p = .28
	12 months	109	51.19 (11.15)	47.65 (10.81)	t (107 df) = 1.69, p = .10
<b>MLHF<sup>2</sup> Total</b>	Baseline	165	45.28 (22.67)	44.54 (22.43)	t (163 df) = .21, p = .83
	6-8 weeks	144	31.30 (24.09)	36.59 (23.10)	t (142 df) = -1.35, p = .18
	12 months	110	30.39 (23.86)	33.63 (24.84)	t (108 df) = .70, p = .49

1. Scale 0 - 100, population norm 50, higher score = better quality of life
2. Scale 0 - 105, higher score = poorer quality of life

**Table 8.3 Differences between groups in change in quality of life between baseline and 6-8 weeks**

	n	Baseline Mean (S.D.)	6-8 weeks Mean (S.D.)	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA
<b>SF-36<sup>1</sup> Physical</b>	Int n=72	28.12 (10.43)	28.71 (12.00)	F (1, 71) = .20, p = .66	F (1, 139) = .04, p = .84
	Con n=70	31.23 (12.47)	29.99 (12.13)	F (1, 69) = .70, p = .41	
<b>SF-36<sup>1</sup> Mental</b>	Int n=72	43.75 (12.62)	48.56 (11.95)	F (1, 71) = 9.67, p = .003	F (1, 139) = 3.19, p = .08
	Con n=70	45.53 (11.07)	46.31 (10.24)	F (1, 69) = .35, p = .56	
<b>MLHF<sup>2</sup> Total</b>	Int n=73	44.68 (21.52)	31.30 (24.09)	F (1, 72) = 26.62, p < .001	F (1, 141) = 3.26, p = .07
	Con n=71	42.97 (21.05)	36.59 (23.06)	F (1, 70) = 5.29, p = .02	

1. Scale 0 - 100, population norm 50, higher score = better quality of life
2. Scale 0 - 105, higher score = poorer quality of life

**Table 8.4 Differences between groups in change in quality of life between baseline and 12 months**

		<b>Baseline Mean (S.D.)</b>	<b>12 months Mean (S.D.)</b>	<b>Post-hoc analysis of within group change from baseline</b>	<b>Between group differences ANCOVA</b>
<b>SF-36<sup>1</sup> Physical</b>	Int n=56	29.24 (9.59)	28.81 (13.89)	F (1, 55) = .08 p = .78	F (1, 105) = .44 p = .51
	Con n=52	30.56 (12.23)	31.17 (13.49)	F (1, 51) = .11 p = .74	
<b>SF-36<sup>1</sup> Mental</b>	Int n=56	43.55 (13.44)	51.19 (11.15)	<b>F (1, 55) = 16.10</b> <b>p &lt; .001</b>	F (1, 105) = 3.76 p = .06
	Con n=52	45.11 (10.67)	47.79 (10.87)	F (1, 51 df) = 2.49 p = .12	
<b>MLHF<sup>2</sup> Total</b>	Int n=56	43.20 (22.74)	30.39 (23.86)	<b>F (1, 55) = 16.61</b> <b>p &lt; .001</b>	F (1, 107) = .31 p = .58
	Con n=54	45.15 (21.61)	33.63 (24.84)	<b>F (1, 53) = 9.09</b> <b>p = .004</b>	

1. Scale 0 - 100, population norm 50, higher score = better quality of life

2. Scale 0 - 105, higher score = poorer quality of life

There was a significant improvement in QoL on the MLHF between baseline and 6-8 weeks in both the intervention (F (1, 72) = 26.62, p < .001) and control groups (F (1, 70) = 5.29, p = .02) but the groups did not differ significantly (F (1, 141) = 3.26, p = .07). At 12 months, QoL was better than at baseline in both the intervention (F (1, 55) = 16.61, p < .001) and control groups (F (1, 53) = 9.09, p = .004). The groups did not differ significantly at 12 months (F (1, 107) = .31, p = .58)

To examine maintenance of change in QoL over the follow-up period, repeated measures ANOVAs were conducted. This analysis could include only those participants who had completed the questionnaires at all three time-points. Results are shown in Table 8.5. Data were available for 106 participants on the SF-36 and 109 participants on the MLHF. Changes over the three time points are shown in Table 8.5. No statistically significant interaction effects were found.

**Table 8.5. Change over time in quality of life**

		<b>Baseline Mean (S.D.)</b>	<b>6-8 weeks Mean (S.D.)</b>	<b>12 months Mean (S.D.)</b>	<b>Group x Time Interaction</b>
<b>SF-36 Physical</b>	Int n=55	29.14 (9.65)	29.12 (12.08)	28.52 (13.84)	F(2,103) = .20, p = .82
	Con n=51	30.64 (12.33)	31.00 (12.45)	31.35 (13.56)	
<b>SF-36 Mental</b>	Int n=55	43.87 (13.34)	48.42 (12.35)	51.30 (11.23)	F(2,103) = .52, p = .59
	Con n=51	45.43 (10.53)	46.14 (9.92)	47.51 (10.78)	
<b>MLHF</b>	Int n=56	43.20 (22.74)	32.14 (25.26)	30.39 (23.86)	F(2,106) = .48, p = .62
	Con n=53	44.42 (21.13)	37.70 (23.36)	33.74 (25.07)	

## 8.2 Psychological wellbeing

### 8.2.1 Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) was completed by 164 patients at baseline, 141 at the 6-8 week follow-up and 110 at the 12 month follow-up. One hundred and seven patients completed the scale at all three time points. ANCOVA tests were performed on 6-8 week and 12 month outcomes, co-varying for baseline scores. Bonferroni adjusted repeated measures analysis of variance (ANOVAs) were then performed to examine change over time within each group.

The groups did not differ significantly on anxiety or depression at 6-8 weeks or 12 months (Table 8.6). Neither were there any statistically significant changes within the groups from baseline to 6-8 weeks nor from baseline to 12 months (Tables 8.7 and 8.8). As no significant differences were found on these tests, further repeated measures ANOVAs to examine maintenance over time were not conducted.

**Table 8.6 Mean (S.D.) Anxiety and Depression Scores**

		n	Intervention	Control	Between group differences
<b>HADS Anxiety, Mean (S.D.)</b>	Baseline	164	6.51 (4.41)	6.55 (4.35)	t (df=162) = -.056, p = .96
	6-8 wks	141	6.23 (4.74)	7.09 (4.57)	t (df=139) = -1.089, p = .28
	12 mths	110	5.80 (4.42)	6.96 (4.55)	t (df=108) = -1.355, p = .18
<b>HADS Depression, Mean (S.D.)</b>	Baseline	164	5.64 (3.54)	5.44 (3.92)	t (df=162) = .352, p = .73
	6-8 weeks	143	6.30 (4.00)	5.72 (3.58)	t (df=139) = .906, p = .37
	12 months	110	5.89 (3.57)	6.09 (3.38)	t (df=108) = -.301, p = .76

**Table 8.7 Differences between groups in change in anxiety and depression between baseline and 6 – 8 weeks**

		Baseline Mean (S.D.)	6-8 weeks Mean (S.D.)	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA
<b>HADS Anxiety</b>	Int n=73	6.52 (4.26)	6.23 (4.74)	F (1, 72) = .32 p = .58	F(1, 138) = 2.49, p = .12
	Con n=68	6.29 (4.18)	7.09 (4.57)	F (1, 67) = 3.22 p = .08	
<b>HADS Depression</b>	Int n=73	5.75 (3.61)	6.30 (4.00)	F (1, 72) = 1.80 p = .18	F(1, 138) = .07, p = .79
	Con n=68	5.01 (3.66)	5.72 (3.58)	F (1, 67) = 2.93 p = .09	

**Table 8.8 Differences between groups in change in anxiety and depression between baseline and 12 months**

		Baseline Mean (S.D.)	12 months Mean (S.D.)	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA
<b>HADS Anxiety</b>	Int n=56	6.39 (4.18)	5.80 (4.42)	F (1, 55) = 1.29, p = .26	F(1, 107) = 2.38, p = .13
	Con n=54	6.52 (4.29)	6.96 (4.55)	F (1, 53) = .62, p = .44	
<b>HADS Depression</b>	Int n=56	5.54 (3.45)	5.89 (3.57)	F (1, 55) = .74, p = .40	F(1, 107) = .18, p = .67
	Con n=54	5.48 (3.99)	6.09 (3.38)	F (1, 53) = 1.79, p = .19	

### 8.2.2 Positive and negative affect

The Positive and Negative Affect Scale (PANAS) (Watson, Clark & Tellegen, 1988) was completed by 163 patients at baseline, 140 at the 6-8 week follow-up and 104 at the 12 month follow-up. One hundred and three patients completed the scale at all three time points. Results for total completers at each time point are given in Tables 8.9 and 8.10. Scores for negative affect at all time points and scores for positive affect at 6-8 weeks and 12 months were not normally distributed, however ANCOVA tests were performed in preference to Mann-Whitney as outlined above. Because of the difference in the size of the sample at each time point, two separate ANCOVAs were computed, one for change over the first two time points and one for change over all three time points. These analyses were performed for positive affect and negative affect. There were no statistically significant time, group or interaction effects for positive or negative affect at any time point (Tables 8.11 and 8.12).

**Table 8.9 Mean (S.D.) scores for positive affect at baseline, 6-8 weeks and 12 months**

<b>PANAS positive affect</b>	<b>n</b>	<b>Intervention</b>	<b>Control</b>	<b>Between group differences</b>
Baseline Mean (SD)	163	23.72 (8.03)	25.79 (9.05)	t (df=161) = -1.54, p = .13
6-8 weeks Mean (SD)	140	23.97 (7.98)	25.68 (8.02)	t (df=138) = -1.24, p = .21
12 months Mean (SD)	104	24.37 (8.79)	26.04 (9.33)	t (df=102) = -.94, p = .35

**Table 8.10 Mean (S.D.) scores for negative affect at baseline, 6-8 weeks and 12 months**

<b>PANAS negative affect</b>	<b>n</b>	<b>Intervention</b>	<b>Control</b>	<b>Between group differences</b>
Baseline Mean (SD)	163	15.70 (5.81)	17.14 (6.93)	t (df=161) = -1.44, p = .15
6-8 weeks Mean (SD)	140	15.33 (5.66)	16.88 (7.38)	t (df=138) = -1.40, p = .16
12 months Mean (SD)	104	14.65 (4.95)	16.34 (5.91)	t (df=102) = -1.59, p = .12



**Table 8.11 Differences between groups in change in positive and negative affect between baseline and 6-8 weeks**

		<b>Baseline Mean (S.D.)</b>	<b>6-8 weeks Mean (S.D.)</b>	<b>Post-hoc analysis of within group change from baseline</b>	<b>Between group differences ANCOVA</b>
<b>PANAS Positive affect</b>	Int n=72	23.73 (8.27)	23.97 (7.97)	F (1, 71) = .09 p = .77	F(1, 137) = .20, p = .66
	Con n=68	25.91 (8.84)	25.68 (8.02)	F (1, 67) = .06 p = .81	
<b>PANAS Negative affect</b>	Int n=72	15.43 (5.74)	15.33 (5.66)	F (1, 71) = .02 p = .89	F(1, 137) = .92, p = .34
	Con n=68	16.54 (6.32)	16.88 (7.38)	F (1, 67) = .18 p = .67	

**Table 8.12 Differences between groups in change in positive and negative affect between baseline and 12 months**

		<b>Baseline Mean (S.D.)</b>	<b>12 months Mean (S.D.)</b>	<b>Post-hoc analysis of within group change from baseline</b>	<b>Between group differences ANCOVA</b>
<b>PANAS Positive Affect</b>	Int n=54	24.53 (8.26)	24.37 (8.79)	F (1, 53) = .20, p = .89	F(1, 101) = .40, p = .53
	Con n=50	25.86 (9.14)	26.04 (9.33)	F (1, 49) = .02, p = .89	
<b>PANAS Negative Affect</b>	Int n=54	15.83 (6.29)	14.65 (4.95)	F (1, 53) = 3.36, p = .07	F(1, 101) = 1.81, p = .18
	Con n=50	16.86 (6.40)	16.34 (5.91)	F (1, 49) = .29, p = .59	

### 8.3 Chapter summary

The results reported in this chapter show that the intervention did not have a statistically significant effect on quality of life or mood.

## **CHAPTER 9**

### **RESULTS - BEHAVIOUR AND COGNITIONS**

The intervention aimed to improve outcomes in the intervention group by changing participants' behaviours and cognitions. This chapter reports the findings for these process variables at 6-8 weeks and 12 months.

#### **9.1 Health Behaviours**

Patients were asked how many minutes exercise they had been taking per week before admission to hospital and again at 6-8 weeks and 12 months post discharge. Patients were also asked if they smoked and how many units of alcohol they drank per week.

##### **9.1.1 Exercise**

Information about duration of exercise per week was completed by 164 patients at baseline, 141 at 6-8 weeks and 108 at 12 months. Of these, 140 completed assessments at both baseline and 6-8 weeks and 104 completed assessments at all three time-points. Results for total completers at each time point are reported in Table 9.1. It should be borne in mind that although the results are reported in minutes per week, the scale is scored in time bands which may tend to overstate the total time spent exercising. This is nevertheless consistent across participants. The data deviated considerably from a normal distribution and did not meet the recommendations of Tabachnick & Fidell (1996) (see section 5.11.2) therefore ANOVA/ANCOVA tests to examine change over time were not performed.

**Table 9.1 Duration of exercise, median (range)**

Exercise minutes p.w.	n	Intervention	Control	Between group differences
Baseline	164	45.0 (0-405)	120.0 (0-630)	Mann-Whitney U = 3042.5, z= -1.064, p=.29
6-8 weeks	141	120.0 (0-405)	60.0 (0-360)	Mann-Whitney U = 2211.0, z= -1.141, p=.25
12 months	108	120.0 (0-555)	120.0 (0-540)	Mann-Whitney U = 1304.5, z= -.951, p=.34

### 9.1.2 Smoking and alcohol intake

There were no significant differences between the groups in smoking behaviour at any of the three assessment times. Although the majority of participants (65.5%) had been smokers at some time in their lives, most were non-smokers at the time of recruitment into the study i.e. they had not smoked for at least 3 months prior to recruitment. Twenty-six patients (16%), thirteen in each group, were smokers at baseline ( $\chi^2$  (df=1) = 0.03, p= .87). Of the 22 current smokers who responded at 6-8 weeks, one intervention group patient had given up smoking (Fisher's Exact, p= 1.00). Eighteen patients responded at 12 months, of whom 2 control group patients had given up smoking (Fisher's Exact, p= .18).

There were no significant differences between the groups in following recommended guidelines on alcohol intake at any of the three assessment times. At baseline, 13 participants (7.9%), 5 in the intervention and 8 in the control group were drinking above the recommended weekly intake of 28 units for men and 21 units for women ( $\chi^2$  (df=1) = 0.96, p= .33). One participant in the control group and no participants in the intervention group drank above the recommended limit at the 6-8 week (Fisher's Exact, p= .49) and 12 month (Fisher's Exact, p= .48) follow-up assessments.

## 9.2 Self-management behaviour

Self-management behaviour was not assessed at baseline because a proportion of study participants would be newly diagnosed with heart failure and therefore would not have been advised to perform the self-management behaviours prior to the index hospital admission. Self-management behaviour was assessed at the 6-8 week and 12 month follow-ups.

The self-management behaviour questionnaire of 8 items was developed for this study. It would not be expected to have a high internal consistency because self-management behaviours are not necessarily highly correlated with each other (Glasgow, Toobert, Riddle et al, 1989) and Cronbach's alpha was found to be .643. However, the questionnaire contained three items related to salt intake so these were combined into a single item using the mean. The Cronbach's alpha for the three items was .683. The commonly recommended level for alpha is  $>.70$  ( DeVellis, 2003) so this score is a little low, however some have suggested that a level of .60 is acceptable (Nunnally & Bernstein, 1994). The combined single item was considered appropriate because the scale then provided one item for each self-management behaviour.

The data for the self-management behaviours deviated considerably from a normal distribution. Patients tended to perform the behaviours all, or almost all, of the time or hardly ever. Although it would have been possible to compare the groups using Mann-Whitney tests, some further analysis (see the analysis of behaviour by subgroup in Chapter 10) would not have been possible with data of this distribution therefore conversion to dichotomous variables with analysis by Chi-squared tests was considered preferable. Data were split according to performance of the behaviour on 6 or 7 days, which was classified as 'full' and 5 days or fewer which was classified as

'incomplete'. This split was chosen both on the basis of examination of the spread of participants' responses and also with reference to adherence research which has tended to classify adherence as following recommendations at least 75% - 85% of the time (Myers & Midence, 1998).

At the 6-8 week assessment, intervention group patients were more likely than controls to report eating a low salt diet, sticking to the recommended daily fluid intake, weighing themselves, checking their ankles for signs of swelling and following exercise recommendations on  $\geq 6$  days (Table 9.2). There was no difference between the groups on taking medication; both reported very high medication adherence with over 97% reporting having taken their medication as prescribed on  $\geq 6$  days.

By the 12 month assessment, performance of some behaviours had decreased, nevertheless a significant difference remained between the intervention and control groups in the percentage of patients who were weighing themselves on  $\geq 6$  days (36.4% v. 3.8%,  $\chi^2$  (df=1) = 17.67,  $p < .001$ ). Although performance of all other self-management behaviours remained higher in the intervention group than controls at 12 months, these differences were not statistically significant (Table 9.2, Figures 9.1, 9.2).

**Table 9.2. Comparison of intervention and control groups on self-management behaviours at 6-8 weeks and 12 months, n (%) performing behaviour on ≥6 days**

<b>Behaviour</b>	<b>Assessment time n</b>	<b>Intervention</b>	<b>Control</b>	<b>Between group differences</b>
<b>Ate low salt diet</b>	6-8 weeks n = 140	31 (43.1)	18 (26.5)	$\chi^2$ (df=1) = 4.23, p = .04
	12 months n = 108	19 (34.5)	11 (20.8)	$\chi^2$ (df=1) = 2.56, p = .11
<b>Took medicine as prescribed</b>	6-8 weeks n = 140	71 (98.6)	66 (97.1)	$\chi^2$ (df=1) = .40, p = .53
	12 months n = 108	53 (96.4)	48 (90.6)	$\chi^2$ (df=1) = 1.50, p = .22
<b>Kept within fluid guidelines</b>	6-8 weeks n = 140	57 (79.2)	40 (58.8)	$\chi^2$ (df=1) = 6.80, p = .009
	12 months n = 106	41 (74.5)	30 (58.8)	$\chi^2$ (df=1) = 2.96, p = .09
<b>Checked weight</b>	6-8 weeks n = 139	48 (67.6)	4 (5.9)	$\chi^2$ (df=1) = 56.51, p <.001
	12 months n = 108	20 (36.4)	2 (3.8)	$\chi^2$ (df=1) = 17.67, p <.001
<b>Checked for signs of oedema</b>	6-8 weeks n = 140	62 (86.1)	40 (58.8)	$\chi^2$ (df=1) = 13.17, p <.001
	12 months n = 108	38 (69.1)	31 (58.5)	$\chi^2$ (df=1) = 1.32, p = .25
<b>Exercised</b>	6-8 weeks n = 140	29 (40.3)	19 (27.9)	$\chi^2$ (df=1) = 2.36, p = .12
	12 months n = 108	19 (34.5)	14 (26.4)	$\chi^2$ (df=1) = .84, p = .36

Figure 9.1 Self-management behaviour at 6-8 weeks

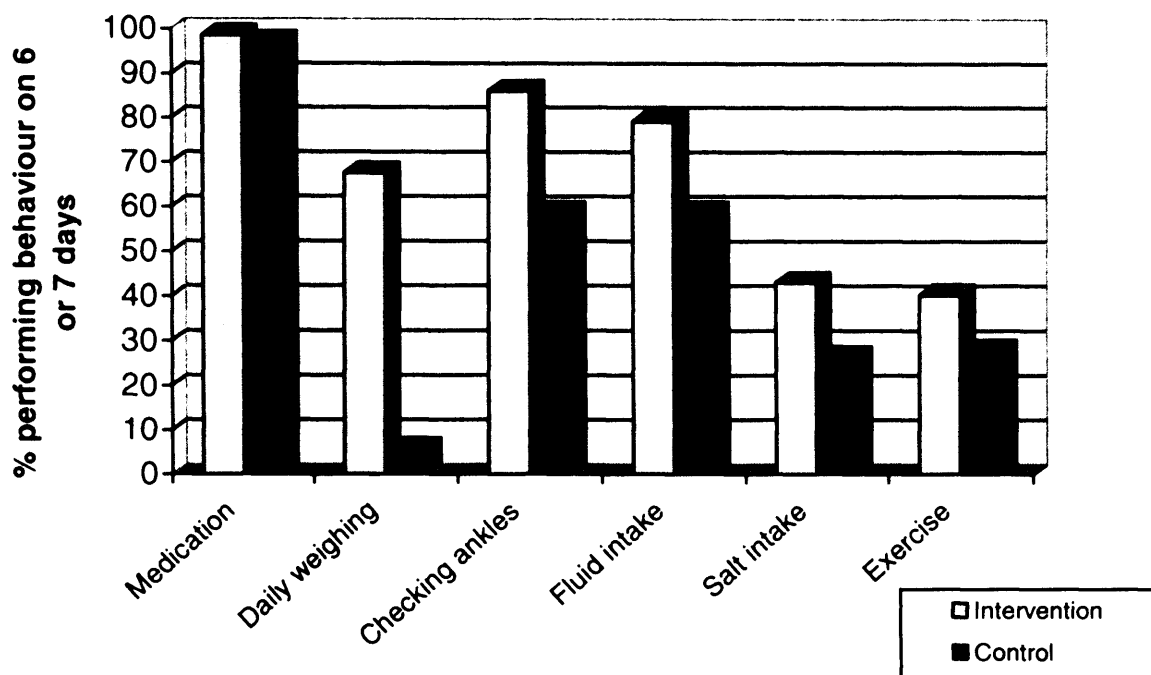
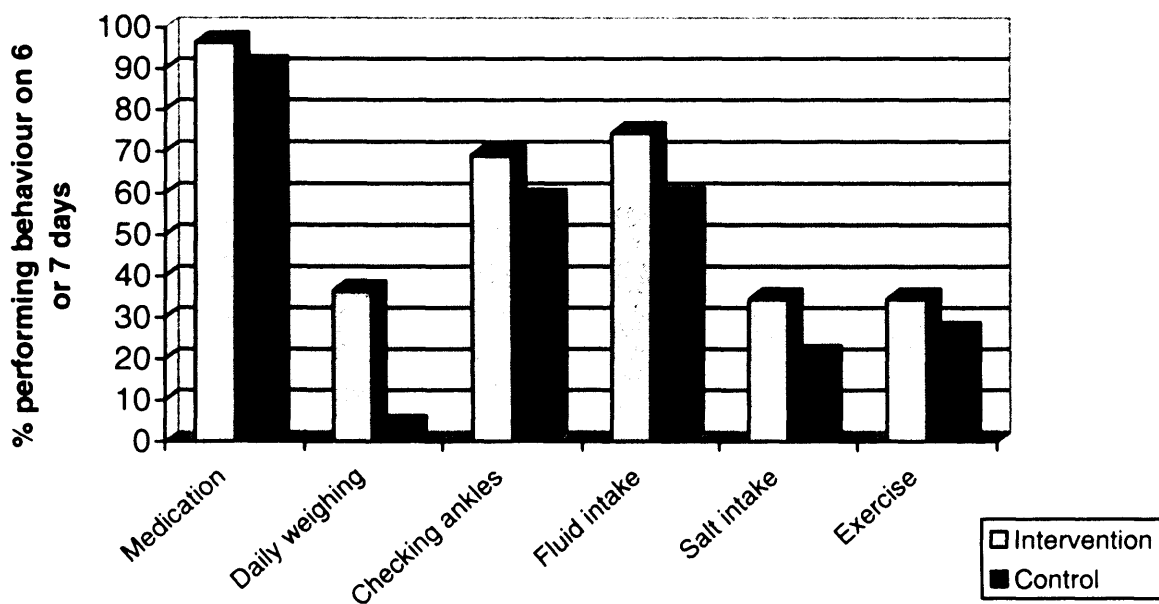


Figure 9.2 Self-management behaviour at 12 months



## **9.3 Cognitions**

### **9.3.1 Self-efficacy**

The heart failure specific self-efficacy questionnaire was completed by 160 patients at baseline and 139 and 104 at 6-8 weeks and 12 months respectively. Ninety-eight participants completed the questionnaire at all three time-points.

As self-efficacy is postulated to be behaviour-specific, each item of the self-efficacy questionnaire was analysed separately to examine differences between the groups at each time-point. The results of this analysis are shown in Table 9.3. At the 6-8 week follow-up, the intervention group reported significantly higher self-efficacy than controls to eat a low salt diet and to follow guidelines on fluid intake. There were no other significant differences between the groups on heart failure self-efficacy.

Analyses of covariance (ANCOVA) were performed to compare the groups at 6-8 weeks and at 12 months, co-varying for baseline scores. Bonferroni adjusted repeated measures analysis of variance (ANOVAs) were then performed to examine change over time within each group. Significant group differences were found at 6-8 weeks only on self-efficacy for salt and fluid intake (results not shown). No significant differences were found at 12 months. Repeated measures ANOVAs to examine maintenance of change over time on self-efficacy for salt and fluid intake did not find any significant effects (results not shown).



**Table 9.3 A comparison of the intervention and control groups on heart failure specific self-efficacy at baseline and 6-8 weeks and 12 months post discharge from hospital**

Self-efficacy to:	Assessment time	n	Intervention	Control	Between group differences
<b>Manage illness</b>	Baseline	160	3.23 (1.21)	3.04 (1.02)	t (df=158) = 1.11, p = .27
	6-8 weeks	139	3.14 (0.98)	3.21 (1.09)	t (df=137) = -.37, p = .71
	12 months	104	3.21 (1.14)	2.98 (1.37)	t (df=102) = .94, p = .35
<b>Monitor signs of change</b>	Baseline	160	3.21 (1.23)	2.95 (1.23)	t (df=158) = 1.34, p = .18
	6-8 weeks	139	3.14 (1.13)	3.04 (1.13)	t (df=137) = .51, p = .61
	12 months	104	3.31 (.96)	2.94 (1.38)	t (df=102) = 1.57, p = .12
<b>Contact doctor/ nurse</b>	Baseline	160	3.47 (1.13)	3.35 (1.18)	t (df=158) = .63, p = .53
	6-8 weeks	139	3.38 (1.09)	3.40 (1.17)	t (df=137) = -.09, p = .93
	12 months	104	3.63 (1.03)	3.19 (1.33)	t (df=102) = 1.90, p = .06
<b>Take medication</b>	Baseline	160	3.83 (1.09)	4.03 (1.01)	t (df=158) = -1.19, p = .24
	6-8 weeks	139	4.14 (0.85)	4.07 (1.00)	t (df=137) = .43, p = .67
	12 months	104	4.17 (0.96)	4.19 (0.93)	t (df=102) = -.10, p = .92
<b>Exercise</b>	Baseline	160	2.59 (1.31)	2.52 (1.36)	t (df=158) = .35, p = .73
	6-8 weeks	138	2.66 (1.25)	2.44 (1.38)	t (df=136) = .97, p = .34
	12 months	104	2.81 (1.28)	2.65 (1.56)	t (df=102) = .55, p = .58
<b>Low salt diet</b>	Baseline	160	3.33 (1.29)	3.13 (1.24)	t (df=158) = 1.03, p = .31
	6-8 weeks	138	3.41 (1.21)	2.96 (1.25)	<b>t (df=136) = 2.19, p = .03</b>
	12 months	104	3.17 (1.34)	3.17 (1.29)	t (df=102) = .00, p = 1.00
<b>Fluid intake</b>	Baseline	160	3.62 (1.03)	3.29 (1.32)	t (df=158) = 1.74, p = .08
	6-8 weeks	139	3.69 (0.97)	3.28 (1.12)	<b>t (df=137) = 2.32, p = .02</b>
	12 months	104	3.46 (1.08)	3.29 (1.32)	t (df=102) = .73, p = .47

### 9.3.2 Beliefs about medication

Beliefs about medication were assessed with the Beliefs about Medication Questionnaire (BMQ) (Horne et al, 1998). Scores for total completers at each time point are given in Table 9.4. There were no significant differences in beliefs about medication between the groups at any of the three time points. ANCOVA, co-varying for baseline scores, did not show any significant group effects at 6-8 weeks or 12

months (results not shown). As no significant differences were found on these tests, further repeated measures ANOVAs to examine maintenance of change over time were not performed.

**Table 9.4. Beliefs about medication**

		n	Intervention	Control	Between group differences
<b>Concerns<sup>1</sup></b>	Baseline	161	2.60 (.88)	2.58 (.90)	t (df=159) = .179, p = .86
	6-8 weeks	138	2.73 (.87)	2.76 (1.02)	t (df=136) = -.210, p = .83
	12 months	107	2.56 (.87)	2.72 (1.02)	t (df=105) = -.860, p = .39
<b>Necessity<sup>2</sup></b>	Baseline	161	4.14 (.65)	4.23 (.65)	t (df=159) = -.859, p = .39
	6-8 weeks	138	4.11 (.62)	4.25 (.59)	t (df=136) = -1.365, p = .18
	12 months	108	4.13 (.74)	4.20 (.67)	t (df=106) = -.550, p = .58

1. Scale 1 – 5, higher score = more concerned about taking medication
2. Scale 1 – 5, higher score = stronger belief in the necessity of medication

### 9.3.3 Illness Beliefs

Patients' illness beliefs are shown in Table 9.5. Unfortunately a large number of respondents did not complete the questionnaire at the 6-8 week follow-up assessment. Belief that heart failure could be cured/controlled reduced between baseline and 12 months in both groups but there was no significant difference between the groups. The groups did not differ significantly in perceived duration of heart failure however perceived duration increased over time in the intervention group but did not change significantly in the control group. There were no statistically significant changes over time or group differences in perceived severity of the consequences of heart failure.

**Table 9.5. Illness beliefs, mean (S.D.)**

IPQ subscale	Assessment time	n	Intervention	Control	Between group differences
<b>Identity</b>	Baseline	158	8.8 (4.6)	9.4 (4.7)	t (df=156) = -.751, p=.45
	6-8 wks	140	8.4 (4.8)	9.2 (4.2)	t (df=131) = -.99, p=.33
	12 mths	100	8.7 (4.9)	9.6 (4.9)	t (df=98) = -.884, p=.378
<b>Cure/control</b>	Baseline	157	3.39 (.52)	3.39 (.64)	t (df=155) = .000, p=1.00
	6-8 wks	88	3.27 (.43)	3.37 (.58)	t (df=86) = -.889, p = .38
	12 mths	102	3.16 (.50)	3.24 (.68)	t (df=100) = -.698, p=.49
<b>Consequences</b>	Baseline	157	3.14 (.60)	3.19 (.79)	t (df=155) = -.479, p= .63
	6-8 wks	88	3.27 (.59)	3.18 (.60)	t (df=86) = .705, p = .48
	12 mths	103	3.19 (.67)	3.21 (.83)	t (df=101) = -.103, p= .92
<b>Timeline</b>	Baseline	157	3.30 (.95)	3.37 (.99)	t (df=155) = -.438, p=.66
	6-8 wks	88	3.67 (.94)	3.55 (.85)	t (df=86) = .605, p=.55
	12 mths	103	3.72 (.93)	3.61 (1.00)	t (df=101) = .546, p = .59

Higher scores = more symptoms, greater perceived control, more severe perceived consequences, longer perceived timeline

**Table 9.6. Differences between groups in change in illness beliefs between baseline and 6-8 weeks, mean (S.D.)**

	n	Baseline Mean (S.D.)	6-8 weeks Mean (S.D.)	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA
<b>Identity</b>	Int n=65	9.1 (4.4)	8.4 (4.8)	F (1,64) = 2.29, p = .14	F (1, 128) = 1.52, p = .22
	Con n=66	9.1 (4.7)	9.2 (4.2)	F (1,65) = .02, p = .88	
<b>Cure/control</b>	Int n=46	3.36 (.50)	3.28 (.43)	F (1,45) = .87, p = .36	F (1,83) = .08, p = .77
	Con n=40	3.50 (.69)	3.37 (.58)	F (1,39) = 2.33, p = .14	
<b>Consequences</b>	Int n=46	3.19 (.50)	3.28 (.60)	F (1,45) = 1.432, p = .24	F (1,83) = .69, p = .41
	Con n=40	3.17 (.68)	3.18 (.60)	F (1,39) = .02, p = .89	
<b>Timeline</b>	Int n=46	3.37 (.97)	3.70 (.89)	<b>F (1,45) = 11.87</b> <b>p = .001</b>	F (1,83) = 1.70, p = .20
	Con n=40	3.44 (1.03)	3.55 (.85)	F (1,39) = .54, p = .47	

Higher scores = more symptoms, greater perceived control, more severe perceived consequences, longer perceived timeline

**Table 9.7. Differences between groups in change in illness beliefs between baseline and 12 months**

	n	Baseline Mean (S.D.)	12 months Mean (S.D.)	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA
<b>Identity</b>	Int n=50	8.8 (4.4)	8.8 (4.9)	F (1,49 df) = .00 p = .96	F (1,95 df) = .17 p = .68
	Con n=48	9.4 (5.0)	9.4 (4.9)	F (1,47 df) = .00 p = .95	
<b>Cure/control</b>	Int n=52	3.36 (.50)	3.15 (.50)	<b>F (1,51 df) = 6.36 p = .02</b>	F (1,97 df) = .07 p = .79
	Con n=48	3.50 (.58)	3.26 (.69)	<b>F (1,47 df) = 8.00 p = .007</b>	
<b>Consequences</b>	Int n=52	3.13 (.61)	3.20 (.68)	F (1,51 df) = .68 p = .41	F (1,98 df) = .26 p = .61
	Con n=49	3.22 (.75)	3.20 (.84)	F (1,48 df) = .04 p = .85	
<b>Timeline</b>	Int n=52	3.44 (.98)	3.73 (.93)	<b>F (1,51 df) = 4.60 p = .04</b>	F (1,98 df) = .22 p = .64
	Con n=49	3.39 (1.02)	3.63 (1.00)	F (1,48 df) = 1.68 p = .20	

Higher scores = more symptoms, greater perceived control, more severe perceived consequences, longer perceived timeline

Repeated measures ANOVAs were not conducted in view of the small number of participants who completed the IPQ at all 3 timepoints (n = 65).

## 9.4 Satisfaction with care

Patients in both groups completed the Client Satisfaction Questionnaire at 6-8 week and 12 month follow-ups. This is an 8-item scale on which the total score can range from 8 to 32. Reported satisfaction with care was very high in both groups with a median score of 30 (range 20-32) in the intervention group at 6-8 weeks and a score of 29 (19-32) at 12 months. Scores in the control group were 29 (20-32) and 30 (16-32) respectively. The groups did not differ significantly at either time point.

## **9.5 Additional assessment performed only with the intervention group**

In addition to the assessments that were conducted to enable comparison between the study groups, additional data were collected from the intervention group. These were conducted to gain patients' feedback about the intervention, to assess the extent to which they utilised the self-management tools provided and whether they contacted the nurse in response to signs of deteriorating heart failure.

### **9.5.1 Intervention group patients' evaluation of the intervention**

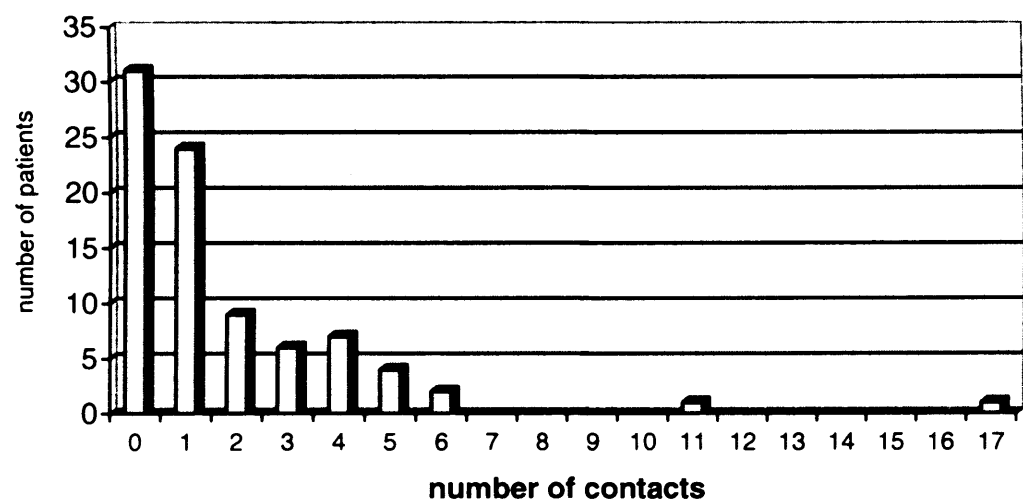
In addition to the assessment of patient satisfaction that was completed by all study patients, the intervention group was asked to complete an evaluation of the intervention. Fifty-five patients in the intervention group (65%) completed evaluations of the intervention at the 12 month follow-up. Of these, 39 (71%) reported finding the intervention helpful and 38 (69%) felt that they were able to put the advice received into practice. For both items this refers to a score of 4 or 5 on a 5-point scale where 1 = 'not at all' and 5 = 'very much'.

### **9.5.2 Patient initiated nurse contact**

Fifty-four patients (64%) in the intervention group contacted the heart failure nurse at least once. A total of 85 calls were received and the number of contacts per patient ranged from 1 to 17 (Figure 9.3). Some patients also made informal contact with the nurse, calling into the clinic when they were visiting the hospital for other routine appointments. Thirty-one patients made no contact with the nurse. Of these, 22 (71%) had at least one event, suggesting that they may have been showing signs of deteriorating heart failure but did not take the suggested action.

Following the calls received by the nurse, 7 patients were admitted to hospital, 45 were asked to come to see the nurse at clinic and 5 were booked for an out-patient appointment with a cardiologist. Twelve calls resulted in an alteration to medication. Sixteen calls did not require any further action; these were generally queries about appointments or medication or to report medication changes made by the patient's G.P.

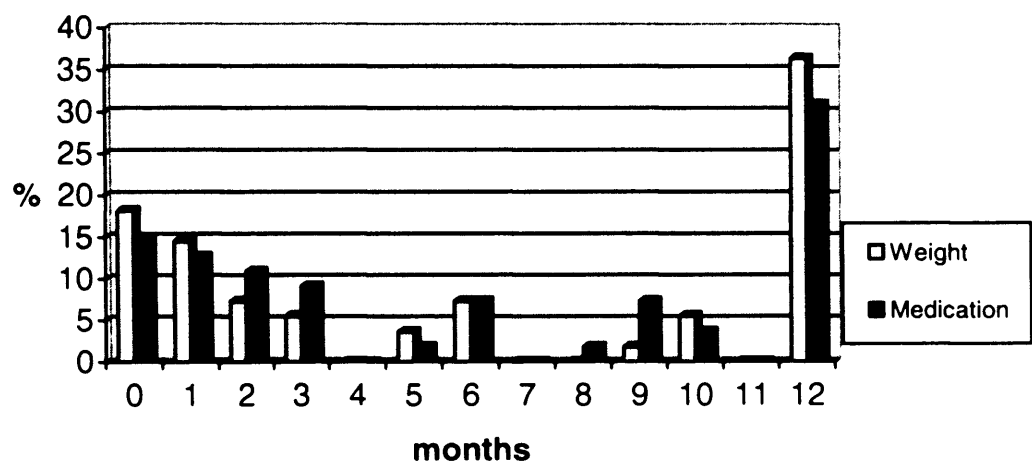
**Figure 9.3 Patient initiated contact with nurse**



**9.5.3 Use of intervention materials**

Fifty-five intervention group patients (65%) completed assessments about use of intervention materials at the 12 month assessment (Figure 9.4). Approximately 15% of those who responded did not use the charts at all and approximately one third were still using them at 12 months.

Figure 9.4 Duration of use of weight and medication charts



## **CHAPTER 10.**

### **RESULTS – PREDICTORS OF OUTCOME AND SUBGROUP ANALYSES**

It had been the intention to examine whether any effects of the intervention on the primary outcome were mediated by cognitions and behaviour but as the intervention did not have an effect on the primary outcomes, this analysis became redundant. It nevertheless remained of interest to examine other factors that may have influenced outcome, and relationships between potential mediators and outcomes, since this analysis could inform the development of future interventions in heart failure. Another important question was whether the intervention, although not effective overall, was effective in some subgroups of patients. Accordingly, a number of secondary analyses were performed to examine:

- The influence of baseline variables on 12 month hospitalisation and mortality
- The influence of baseline variables on those variables targeted by the intervention i.e. behaviour and cognitions
- The influence of behaviour at 6-8 weeks on 12 month hospitalisation and mortality
- The effectiveness of the intervention within subgroup(s) of patients

#### **10.1 Baseline predictors of 12 month hospitalisation and mortality**

One of the areas of interest for this study was to explore whether baseline characteristics could be used to identify who would be most likely to benefit from the intervention. To examine baseline predictors of the occurrence of death, death or all-cause admission and death or heart failure admission, logistic regressions were performed (see methods Chapter 5, section 5.11.5). Given the relatively small number



of patients who had had an event at 90 days i.e. 'cases' for the purpose of regression analysis, the analyses were performed to predict only the 12 month outcomes. As the study groups did not differ at baseline or in the outcomes of death or hospital admission, group allocation was not entered into the regression analyses.

Table 10.1 shows the baseline variables that were significant predictors of one or more of the outcomes in univariate analyses. The risk of mortality was higher in those of older age, who spent longer in hospital during the index admission, and reported lower generic and HF specific self-efficacy to manage their illness at baseline. Owing to the small number of 'cases' for this outcome (29 deaths), a maximum of 3 independent variables (IVs) could be entered into the multivariate logistic regression. Age and patients' self-efficacy to manage their heart failure remained significant (Table 10.2).

The baseline variables that most consistently predicted hospital admission or the combined outcomes of death or readmission were comorbidity, whether the diagnosis of heart failure was new or existing and the number of symptoms attributed to heart failure, assessed by the IPQ Identity subscale. A greater number of comorbid illnesses and a greater number of symptoms attributed to heart failure were both associated with an increased risk of an event whereas those with newly diagnosed heart failure were at less risk of an event than patients for whom the diagnosis had been longer standing. When entered into the multivariate logistic regression analyses (Tables 10.3 – 10.6), only comorbidity and a new diagnosis of heart failure remained significant.

**Table 10.1 Univariate predictors of 12 month outcomes using logistic regression analyses. Wald statistic reported.**

Predictor variable <sup>§</sup>	Mortality	All cause admission	Death or all cause admission ('All-cause event')	HF admission	Death or HF admission ('HF event')
Number of events	29	91	100	47	61
<b>Baseline variables:</b>					
Age	6.171*	-	-	-	-
Comorbidity	-	8.916**	9.213**	7.067**	8.234**
HF aetiology (ischaemic / non-ischaemic)	-	-	-	-	4.103*
New HF	-	4.310*	7.324**	10.652***	15.133***
Duration (days) of index admission	6.867**	-	-	-	-
NYHA at study recruitment	-	-	-	-	5.470*
IPQ Identity	-	4.523*	4.548*	6.345*	7.463**
IPQ Cure/control	-	-	-	-	-
Generic self-efficacy	4.389*	-	-	-	-
HF self-efficacy to manage illness <sup>†</sup>	9.219**	-	6.114*	-	6.104*
HF self-efficacy to keep to fluid guidelines	-	-	-	-	4.143*
<b>6-8 week behaviour:</b>					
Weekly exercise duration	5.425*	4.203*	5.766*	-	-
Self-mgt behaviour - daily weighing	4.060*	-	-	-	-

p<.05, \*\*p≤.01, \*\*\*p≤.001

§ Only variables that were statistically significant predictors of at least one outcome variable are included in the table

† Question 1 of the HF self-efficacy scale - How confident are you that you can do all the things necessary to manage your heart failure on a regular basis?

**Table 10.2 Baseline predictors of 12 month mortality.  
Multivariate logistic regression analysis**

<b>n = 165</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
Age	.046	.021	4.653	1	.03	1.047
Duration of index hospital stay	.015	.012	1.581	1	.21	1.015
HF self-efficacy to manage illness	-.528	.209	6.354	1	.01	.590
Constant	-3.759	1.741	4.662	1	.03	.023
Nagelkerke R <sup>2</sup>	.172					

**Table 10.3 Baseline predictors of death or *all cause* readmission to hospital  
Multivariate logistic regression analysis**

<b>n = 156</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
New HF	-.824	.369	4.988	1	.03	.439
Comorbidity	.533	.211	6.374	1	.01	1.704
IPQ Identity	.032	.040	.625	1	.43	1.032
HF self-efficacy to manage illness	-.303	.169	3.198		.07	.739
Constant	1.050	.742	2.005	1	.16	2.858
Nagelkerke R <sup>2</sup>	.182					

**Table 10.4 Baseline predictors of death or readmission to hospital for *heart failure*. Multivariate logistic regression analysis**

<b>n = 156</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
New HF	-1.219	.392	9.658	1	.002	.296
Comorbidity	.458	.210	4.770	1	.03	1.581
IPQ Identity	.047	.045	1.105	1	.29	1.049
NYHA at study recruitment	.206	.369	.311	1	.58	1.229
Aetiology	.606	.380	2.544	1	.11	1.833
HF self-efficacy to manage illness	-.266	.185	2.082		.15	.766
HF self-efficacy to keep to fluid guidelines	-.212	.172	1.513		.22	.809
Constant	-.101	1.268	.006	1	.94	.904
Nagelkerke R <sup>2</sup>	.282					

**Table 10.5 Baseline predictors of *all cause* readmission to hospital**

n = 156	B	S.E.	Wald	df	p	Exp(B)
New HF	-.692	.348	3.954	1	.05	.500
Comorbidity	.518	.198	6.844	1	.01	1.678
IPQ Identity	.039	.038	1.020	1	.31	1.039
Constant	-.272	.469	.378	1	.56	.762
Nagelkerke R <sup>2</sup>	.132					

**Table 10.6 Baseline predictors of readmission to hospital for *heart failure***

n = 156	B	S.E.	Wald	df	p	Exp(B)
New HF	-1.178	.385	9.376	1	.002	.308
Comorbidity	.415	.201	4.277	1	.04	1.514
IPQ Identity	.060	.044	1.920	1	.16	1.062
Constant	-1.396	.533	6.857	1	.009	.247
Nagelkerke R <sup>2</sup>	.181					

## 10.2 Baseline predictors of cognitions and self-management behaviour

An important aim of the self-management intervention was to change cognitions and behaviour and it was hypothesised that these changes would have a beneficial impact on health outcomes i.e. that they would mediate the effect of the intervention on health outcomes. It had therefore been the intention to perform mediator analysis to examine this relationship but as the intervention did not have an effect on the primary outcomes, this analysis was not possible (see section 5.11.5 for the requirements of mediator analysis). It nevertheless remained of interest to examine whether change in cognitions and behaviour could be predicted from baseline variables as this could help to inform future interventions. As the intervention had not resulted in changes in cognitions, these variables were not examined further. However, the intervention group had reported greater performance of self-management behaviours than controls at the 6-8 week follow-up assessment therefore the influence of baseline variables on 6-8 week

behaviour and the relationship between behaviour and hospitalisation and mortality outcomes were examined.

Univariate logistic regression analyses were performed to examine whether baseline variables could predict 6-8 week behaviour and whether 6-8 week behaviour predicted 12 month health outcomes. The baseline variables that significantly predicted behaviours in univariate analysis are shown in Table 10.7. Multivariate logistic regressions to predict daily weighing, monitoring for oedema and fluid management are shown in Tables 10.8, 10.9 and 10.10 respectively. Group allocation remained a significant predictor in multivariate analyses of weight monitoring, monitoring oedema and keeping to fluid recommendations with intervention group patients more likely to perform the behaviours. Besides group allocation, age was also a significant predictor of weight monitoring, with older patients less likely to weigh themselves on  $\geq 6$  days. Perceived duration of heart failure (IPQ timeline) was a significant predictor of monitoring oedema, with patients who perceived the illness to have a longer timeline more likely to monitor on  $\geq 6$  days. No variables remained significant in the multivariate analyses for eating a low salt diet and exercise (results not shown). Analysis was not performed for adherence to medication as almost the whole sample reported full adherence.

**Table 10.7 Univariate logistic regression analysis of baseline predictors of self- management behaviours. Wald statistic reported**

	Daily weights	Check ankles	Salt intake	Fluid intake	Exercise
Number performing / not performing behaviour ≥6 days	52/87	102/38	49/91	97/43	48/92
<b>Study group allocation</b>	37.305***	12.184***	4.165*	6.601**	
<b>Demographics</b>					
Age	5.646*			4.219*	
<b>Symptoms</b>					
IPQ identity			5.821*		4.846*
<b>Beliefs</b>					
IPQ Consequences					5.386* (consequences)
IPQ Cure/control				4.713* (cure/control)	
IPQ Timeline		4.688* (timeline)			
BMQ Necessity			4.258* (BMQ concerns)		
BMQ Concerns					5.163* (manage illness)
HF self-efficacy:					6.292* (monitor change)
<i>Manage illness</i>					
<i>Monitor change</i>		4.891* (monitor change)			
<i>Contact HCP</i>					
<i>Take medication</i>					9.403** (exercise)
<i>Exercise</i>					
<i>Low salt diet</i>		5.117* (low salt)	5.386* (low salt)		
<i>Fluid recommendations</i>				4.018* (fluid)	
General self-efficacy					
<b>Mood</b>					
HADS Anxiety			4.878* (anxiety)		
HADS Depression					4.868* (depression)
PANAS Positive					
PANAS Negative				5.383* (PANneg)	

\* p<.05, \*\*p≤.01, \*\*\*p≤.001

**Table 10.8 Baseline predictors of weight monitoring at 6-8 weeks – multivariate logistic regression analysis**

<b>n = 139</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
Group allocation	3.911	.661	35.015	1	.000	49.969
Age	-.058	.020	8.875	1	.003	.943
Constant	1099	1.303	.712	1	.399	3.002
Nagelkerke R <sup>2</sup>	.562					

**Table 10.9 Baseline predictors of monitoring oedema at 6-8 weeks – multivariate logistic regression analysis**

<b>n = 135</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
Group allocation	-1.650	.473	12.181	1	.000	.192
Self-efficacy - monitor change	.317	.181	3.048	1	.081	1.372
Self-efficacy – low salt diet	.308	.188	2.685	1	.101	1.361
IPQ Timeline	.590	.233	6.384	1	.012	1.804
Constant	-.182	1.219	.022	1	.882	.834
Nagelkerke R <sup>2</sup>	.260					

**Table 10.10 Baseline predictors of keeping to fluid guidelines at 6-8 weeks – multivariate logistic regression analysis**

<b>n = 135</b>	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>p</b>	<b>Exp(B)</b>
Group allocation	-1.046	.424	6.0691	1	.014	.351
Age	.030	.016	3.407	1	.065	1.030
IPQ cure/control	-.753	.399	3.553	1	.059	.471
Self-efficacy – fluid	.323	.182	3.170	1	.075	1.382
PANAS negative mood	-.055	.034	2.655	1	.103	.947
Constant	2.753	2.174	1.603	1	.206	15.682
Nagelkerke R <sup>2</sup>	.221					

### **10.3 The influence of self-management behaviour at 6-8 weeks on 12 month hospitalisation and mortality**

Table 10.1 shows the 6-8 week behaviours that were significant predictors of one or more of the 12 month outcomes in univariate analyses. Although exercise duration at baseline was not associated with outcomes, a longer duration of exercise at 6-8 weeks was associated with a lower risk of death and all-cause readmission to hospital. When entered into multivariate logistic regression analyses in which age was entered in the first step, exercise remained a significant predictor of all-cause admission to hospital but not of mortality or the combined outcome of death or admission to hospital. However, if comorbidity, a variable likely to influence exercise duration, was entered into the regression, exercise duration was no longer significant (regression tables not shown).

Of the self-management behaviours, self-monitoring by daily weighing was a predictor of mortality but not readmission to hospital. However, when entered into multivariate logistic regression analyses in which age was entered in the first step, weight monitoring was no longer statistically significant (regression table not shown). Older patients were less likely than younger patients to monitor their weight on  $\geq 6$  days. None of the other self-management behaviours were significant predictors of hospitalisation or mortality.



## 10.4 Sub-group analysis

The analysis in sections 10.1 and 10.2 examined whether it was possible to predict 12 month study outcomes from the variables measured at baseline. That analysis provides an indication of some of the variables that may need to be targeted in order to bring about change. An additional important analysis is to examine whether the intervention, although not effective overall, was effective in some sub-groups of patients. This has been reported in a previous study, by Riegel et al (2000), who found that their intervention was not effective overall but did have a beneficial effect in patients who were moderately symptomatic. It was therefore decided to conduct post-hoc analyses to examine whether the current intervention also had an effect among some sub-groups of patients who could be identified from baseline variables. The hazards of sub-group analysis (Lagakos, 2006) are recognised, and findings therefore need to be interpreted with caution, nevertheless this analysis has potential value. It is important to examine whether different types of patients respond differently to the intervention. Any significant findings that emerge, whilst not conclusive, do provide indicators of important areas for further examination in future studies.

The studies reviewed in Chapter 3 identified a number of demographic and disease-related factors that may have an effect on self-management of heart failure. These were age, NYHA, comorbid illness and whether the diagnosis of heart failure was new or longer-standing (see sections 3.4.1 and 3.4.2). Accordingly these variables were chosen as subgroups in which to examine whether the intervention was effective. To conduct this analysis, age and number of comorbid illnesses had to be transformed from continuous to categorical variables, which was carried out based on examination of the distribution of the data. Comorbidity was divided into three subgroups with 0, 1 and  $\geq 2$  comorbidities. Age was also divided into three subgroups, aged  $\leq 68$ , 69 – 79 and  $\geq 80$ . Differences between the intervention and control group in each subgroup

were then examined by conducting separate  $\chi^2$  analysis. Tables 10.11 and 10.12 show the differences between intervention and control groups within each subgroup in 90 day and 12 month outcomes respectively.

An important issue to consider in this analysis is that there are many other potential subgroups that could have been examined. Subgroups could arise in demographic and clinical variables, behaviours, beliefs, mood and social variables. For example, it would have been possible to examine whether the intervention performed differently in men and women, in depressed versus non-depressed patients, and so on. However, this would require a very large number of statistical tests, increasing the risk of making a Type I error.

The subgroup analysis did not find any difference between the intervention and control groups within the subgroups of age, NYHA or comorbid illnesses. However, in the subgroup of patients who were newly diagnosed with heart failure, fewer patients in the intervention group were readmitted for heart failure or had a HF event i.e. combined outcome of death or readmission for heart failure and patients in the intervention group spent fewer days in hospital for heart failure than controls in the 12-months following discharge (Tables 10.11, 10.12 and 10.13).

**Table 10.11 Differences in 90-day outcomes between intervention and control within sub-groups**

90 days							
Subgroup	All cause				Heart Failure		
	Mortality	Readmitted to hospital	Died or readmitted to hospital	Total days in hospital**	Readmitted to hospital	Died or readmitted to hospital	Total days in hospital**
<b>Age</b>							
≤68, n=55	Fisher's*, p=1.00	$\chi^2 = .041$ , p=.84	$\chi^2 = .231$ , p=.63	Z=-.195, p=.85	$\chi^2 = .164$ , p=.69	$\chi^2 = .005$ , p=.94	Z=-.277, p=.78
69 – 79, n=56	Fisher's, p=1.00	$\chi^2 = .025$ , p=.88	$\chi^2 = .000$ , p=1.00	Z=-.099, p=.92	$\chi^2 = .078$ , p=.78	$\chi^2 = .049$ , p=.82	Z=-.235, p=.81
80+, n=54	Fisher's, p=1.00	$\chi^2 = .254$ , p=.61	$\chi^2 = .015$ , p=.90	Z=-.402, p=.69	$\chi^2 = 1.037$ , p=.31	$\chi^2 = .020$ , p=.89	Z=-.989, p=.32
<b>NYHA</b>							
I/II, n=124	Fisher's, p=1.00	$\chi^2 = .540$ , p=.46	$\chi^2 = .024$ , p=.88	Z=-.398, p=.69	Fisher's, p=.14	$\chi^2 = .230$ , p=.63	Z=-1.595, p=.11
III/IV, n=41	Fisher's, p=.66	$\chi^2 = .201$ , p=.54	$\chi^2 = .605$ , p=.44	Z=-.102, p=.92	Fisher's, p=.73	$\chi^2 = .595$ , p=.44	Z=-.334, p=.74
<b>New/Existing</b>							
New HF, n=90	Fisher's, p=.44	$\chi^2 = .229$ , p=.63	$\chi^2 = .198$ , p=.66	Z=-.311, p=.76	Fisher's, p=.06	Fisher's, p=.12	<b>Z=-2.054, p=.04</b>
Existing HF, n=75	Fisher's, p=.13	$\chi^2 = .107$ , p=.74	$\chi^2 = .258$ , p=.61	Z=-.166, p=.87	Fisher's, p=1.00	Fisher's, p=.31	Z=-.104, p=.92
<b>Co-morbidity</b>							
0, n = 49	Fisher's, p=1.00	Fisher's, p=.26	$\chi^2 = .262$ , p=.61	Z=-1.240, p=.22	Fisher's, p=.15	Fisher's, p=.44	Z=-1.711, p=.09
1, n = 66	Fisher's, p=1.00	$\chi^2 = .000$ , p=1.00	$\chi^2 = .067$ , p=.80	Z=-.110, p=.91	Fisher's, p=.48	$\chi^2 = .096$ , p=.76	Z=-1.043, p=.30
2 or more, n = 50	Fisher's, p=.46	$\chi^2 = .297$ , p=.59	$\chi^2 = .703$ , p=.40	Z=-.804, p=.42	Fisher's, p=.49	$\chi^2 = 1.290$ , p=.26	Z=-.806, p=.42

\*Fisher's Exact Test

\*\* Mann-Whitney U tests performed, z statistic reported

**Table 10.12 Differences in 12 month outcomes between intervention and control within sub-groups**

Subgroup	12 months						
	All cause				Heart Failure		
	Mortality	Readmitted to hospital	Died or readmitted to hospital	Total days in hospital**	Readmitted to hospital	Died or readmitted to hospital	Total days in hospital**
<b>Age</b>							
≤68, n=55	Fisher's*, p=.61	$\chi^2 = .022$ , p=.88	$\chi^2 = .014$ , p=.91	Z=-.354, p=.72	$\chi^2 = 1.547$ , p=.21	$\chi^2 = .900$ , p=.34	Z=-.787, p=.43
69 – 79, n=56	Fisher's, p=1.00	$\chi^2 = .021$ , p=.88	$\chi^2 = .044$ , p=.83	Z=-.183, p=.86	$\chi^2 = .025$ , p=.88	$\chi^2 = .044$ , p=.83	Z=-.230, p=.82
80+, n=54	Fisher's, p=.13	$\chi^2 = .034$ , p=.85	$\chi^2 = .254$ , p=.61	Z=-.292, p=.77	$\chi^2 = 2.658$ , p=.10	$\chi^2 = 1.718$ , p=.19	Z=-1.510, p=.13
<b>NYHA</b>							
I/II, n=124	$\chi^2 = .537$ , p=.46	$\chi^2 = .046$ , p=.83	$\chi^2 = .420$ , p=.52	Z=-.180, p=.86	$\chi^2 = 3.115$ , p=.08	$\chi^2 = 1.303$ , p=.25	Z=-1.639, p=.10
III/IV, n=41	$\chi^2 = .067$ , p=.80	$\chi^2 = .016$ , p=.90	$\chi^2 = .010$ , p=.92	Z=-.242, p=.81	$\chi^2 = .266$ , p=.61	$\chi^2 = .605$ , p=.44	Z=-.193, p=.85
<b>New/Existing</b>							
New HF, n = 90	Fisher's, p=.052	$\chi^2 = .037$ , p=.85	$\chi^2 = .000$ , p=.99	Z=-.567, p=.57	<b>Fisher's, p=.01</b>	<b><math>\chi^2 = 6.307</math>, p=.01</b>	<b>Z=-2.545, p=.01</b>
Existing HF, n=75	Fisher's, p=.79	$\chi^2 = .830$ , p=.36	$\chi^2 = .155$ , p=.69	Z=-.574, p=.57	Fisher's, p=.64	$\chi^2 = .035$ , p=.85	Z=-.406, p=.69
<b>Co-morbidity</b>							
0, n = 49	Fisher's, p=.26	$\chi^2 = .000$ , p=1.00	$\chi^2 = .246$ , p=.62	Z=-.090, p=.93	Fisher's, p=.15	$\chi^2 = 2.522$ , p=.11	Z=-1.451, p=.15
1, n = 66	$\chi^2 = .096$ , p=.76	$\chi^2 = .061$ , p=.81	$\chi^2 = .254$ , p=.61	Z=-.718, p=.47	$\chi^2 = .713$ , p=.40	$\chi^2 = .273$ , p=.60	Z=-.959, p=.34
2 or more, n = 50	Fisher's, p=1.00	$\chi^2 = .244$ , p=.62	$\chi^2 = .024$ , p=.88	Z=-.020, p=.98	$\chi^2 = .384$ , p=.54	$\chi^2 = .074$ , p=.79	Z=-.281, p=.78

\*Fisher's Exact Test

\*\* Mann-Whitney U tests performed, z statistic reported

**Table 10.13 Mortality and hospital readmission in the 90 days and 12 months following discharge in patients with newly diagnosed heart failure**

	90 days				12 months			
n	Total 90	I 43	C 47	Statistical significance	Total 90	I 43	C 47	Statistical significance
Mortality, n(%)	7 (7.8)	2 (4.7)	5 (10.6)	Fisher's, p=.44	11 (12.2)	2 (4.7)	9 (19.1)	Fisher's, p=.05
Patients who died or had at least one <b>all cause</b> readmission, n (%)	25 (27.8)	11 (25.6)	14 (29.8)	$\chi^2$ (df=1)=.198, p=.66	46 (51.1)	22 (51.2)	24 (51.1)	$\chi^2$ (df=1)=.000, p=.99
Patients with at least one <b>all cause</b> readmission, n (%)	23 (25.6)	10 (23.3)	13 (27.7)	$\chi^2$ (df=1)=.229, p=.63	43 (47.8)	21 (48.8)	22 (46.8)	$\chi^2$ (df=1)=.037, p=.85
Total number of <b>all cause</b> readmissions(no. pp)	29 (.18)	12 (.28)	17 (.36)	Mann-Whitney U=963.0, z=-.504, p=.61	72 (.80)	36 (.84)	36 (.77)	Mann-Whitney U=977.5, z=-.292, p=.77
Total <b>all cause</b> days in hospital (no. p.p.)	385 (4.3)	145 (3.4)	240 (5.1)	Mann-Whitney U=981.0, z=-.311, p=.76	1424 (15.82)	765 (17.79)	659 (14.02)	Mann-Whitney U=945.5, z=-.567, p=.57
Patients who died or had at least one <b>HF</b> readmission, n (%)	12 (13.3)	3 (7.0)	9 (19.1)	Fisher's, p=.06	<b>21 (23.3)</b>	<b>5 (11.6)</b>	<b>16 (34.0)</b>	$\chi^2$ (df=1) = 6.307, p=.01
Patients with at least one <b>HF</b> readmission, n (%)	8 (8.9)	1 (2.3)	7 (14.9)	Fisher's, p=.12	<b>16 (17.8)</b>	<b>3 (7)</b>	<b>13 (27.7)</b>	Fisher's, p = .01
Total number of <b>HF</b> readmissions (no. pp)	9 (.10)	1 (.02)	8 (.17)	Mann-Whitney U=883.0, z=-2.088, p=.04	<b>18 (0.20)</b>	<b>3 (0.07)</b>	<b>15 (0.32)</b>	Mann-Whitney U=798.5, z=-2.580, p=.01
Total days in hospital for <b>HF</b> (no. p.p.)	102 (1.13)	14 (.33)	88 (1.87)	Mann-Whitney U=885.0, z=2.054, p=.04	<b>317 (3.52)</b>	<b>37 (0.86)</b>	<b>280 (5.96)</b>	Mann-Whitney U=800.5, z=-2.545, p=.01

#### **10.4.1 Predictors of outcome in subgroups**

An interesting question then arises about what factors may have influenced the outcome for this subgroup i.e. if the findings can be explained by those variables that were addressed in the intervention - behaviour and cognition. Although mood was not directly targeted by the intervention it was also included in this analysis because it has been shown to be an important predictor of outcome in other studies and it may be expected to change as behaviour and cognitions change. To examine this question, it was necessary to examine whether there was a differential effect of the intervention on behaviour, cognition and mood according to whether or not heart failure was newly diagnosed i.e. an interaction effect. A series of ANCOVA tests, covarying for baseline, were performed for exercise duration, self-efficacy, medication beliefs, illness beliefs, anxiety, depression, positive and negative mood, with study group and a new or existing diagnosis of heart failure both entered as between-subject factors. This analysis did not find any significant interaction effects, indicating that the process variables did not change differentially by study group within the subgroups. Examination of the number of out-patient appointments and nurse contacts also found no differences between patients according to whether the diagnosis was new or existing.

As performance of self-management behaviours had been transformed into dichotomous variables, and had not been assessed at baseline,  $\chi^2$  tests, rather than ANCOVAs were used. This analysis examined whether there was a difference in behaviour at 6-8 weeks between the intervention and control groups in newly diagnosed patients that was not found in patients with a longer standing diagnosis. No significant differences were found.

# **CHAPTER 11**

## **DISCUSSION**

### **11.1 Introduction**

The aim of this study was to design a self-management intervention for people admitted to hospital with heart failure, to describe the intervention in detail in a manual and to evaluate the intervention in a randomised controlled trial. This chapter discusses the efficacy of the intervention on the primary and secondary outcomes, possible explanations for the findings and suggestions for how the intervention could be improved. The chapter also discusses directions for future research.

In considering the findings of this study, it is important to first of all place the intervention in the context of other interventions that have been implemented in heart failure. In terms of its effect on clinical outcomes, this study will inevitably be compared with disease management programmes which are the most common current approach to improving outcomes in heart failure. It is important that the vast majority of heart failure programmes that have been published to date are not self-management interventions but rather disease management programmes, which aim to reduce hospital admissions and mortality through improving the delivery of recommended clinical care. As discussed in Chapter 3, the beneficial outcomes of these interventions would appear to be explained by the optimisation of medication and/or closer monitoring of patients by health professionals to detect and treat early signs of worsening heart failure. Although most programmes include education about self-management behaviours, it is not their primary focus and they do not focus on techniques to improve self-management. The current study was one of the first to try to improve outcomes for patients with heart failure through enhancing self-management.

As such, it is not strictly comparable with the many disease management programmes that have been reported in the heart failure literature.

## **11.2 Acceptability of the intervention**

Over 80% of those approached agreed to take part in the study, suggesting that a large proportion of patients with heart failure would be interested in participating in a self-management programme. Since a proportion of those who refused may have been declining participation in the research study rather than the intervention, actual acceptability of the intervention may be greater than this figure suggests.

Three different factors provided indications that the intervention was acceptable to patients. Firstly, there was a low attrition rate with less than 6% of those randomised dropping out of the intervention sessions. Patients were also asked to provide feedback about the intervention and of those who did, most reported finding the intervention helpful. This was supported by the finding that a high proportion of intervention patients (almost two-thirds) made contact with the heart failure nurse.

The acceptance rate into the study is higher than in many other studies of self-management interventions (e.g. Glasgow, Eakin & Toobert, 1996) which may be due to a number of factors. Firstly, recruitment took place on an in-patient ward where patients may be more likely to accept an intervention that could be of help. Secondly, participants had been admitted to hospital with what was clearly a major life-threatening illness. Thirdly, in contrast to many self-management interventions, the short duration of the intervention meant that the time and effort required to participate was relatively low.



### **11.3 Consequences of the self-management intervention on follow-up care**

The intervention and control groups received similar numbers of follow-up cardiology appointments. Although slightly higher in the intervention group, this was not statistically significant so while the nurse may have referred intervention group patients for cardiology appointments where considered clinically necessary, the difference made to the overall number of visits was not large. Prescribed medication also did not differ between the groups. These findings indicate that any differences between the intervention and control groups in study outcomes can be attributed to the self-management intervention rather than differences in cardiology care.

There had been some concern when designing the study that providing patients with telephone access to the nurse would lead to an unmanageable demand on the service. In practice, there was a total of 85 calls to the nurse, an average of one per patient in the intervention group of which 45 led to patients being asked to visit the nurse at the clinic.

### **11.4 Intervention efficacy - hospitalisation and mortality**

It had been hypothesised that patients in the intervention group would experience lower rates of readmission to hospital than the standard care control group in the 90 days and 12 months following discharge from the index admission and lower 12-month mortality. These hypotheses were not supported for the study sample as a whole.

There are a number of possible reasons why an overall impact on outcomes was not achieved. It was hypothesised that the intervention would have an effect on hospitalisation and possibly mortality (although the study was not powered to find the latter effect) by improving self-efficacy to perform self-management behaviours and

altering beliefs that could act as a barrier to performing these behaviours. These mechanisms would lead to better performance of the self-management behaviours which would in turn reduce hospitalisation and possibly mortality. The following sections will discuss the impact of the intervention on self-management behaviour, self-efficacy and medication and illness beliefs and their impact on outcomes. They will also consider ways in which the intervention could possibly have been altered that may have resulted in improved outcomes.

First of all, it is important to examine how the primary outcomes of this study compare with other interventions that have been developed for heart failure, but bearing in mind the qualification made in the second paragraph of this chapter. Reviews suggest that disease management programmes in heart failure have been successful in reducing hospital admission, although there is variation in their efficacy (see Chapter 2). At first glance it may appear therefore that the findings of the current study compare unfavourably with other approaches. However, closer examination reveals that this is not necessarily the case.

One possible explanation for the lack of an overall significant difference between the intervention and control groups in these outcomes may be the high quality of standard care received by the control group, making improvement on standard care more difficult. Comparison of outcomes for the standard care control group in this study with the outcomes of other studies supports this possibility. Many of the heart failure programmes published to date have compared an intervention group who received improved medical care with a control group who did not. In the current study, patients in both the intervention and control groups were discharged from hospital only when they were clinically stable on maximum tolerated heart failure medication and both groups also received out-patient follow up by a cardiologist as often as considered clinically necessary. When comparing study findings it is important therefore to

examine not only whether studies find statistically significant differences between the intervention and control groups but also to compare different studies on the rate of events in the control groups. This gives an indication of the effect of differences in standard care between studies (although it is recognised that any differences between study populations are also important). For example, in a study by Stromberg, Martensson, Fridlund et al (2003), which reported statistically significant benefits of a nurse-led heart failure clinic, total days in hospital in the first 3 months averaged 6.7 days in the intervention group and 11 days in the control group, compared with 5.8 days and 6.1 days respectively within 90 days in the current study. In a more recent study of a brief education programme (Koelling et al, 2005), which reported statistically significant benefits for the intervention group, approximately half the control group had died or been readmitted to hospital within 90 days of discharge, compared with 33.8% in the current study, while the rates for the intervention groups was similar in both studies. Dunagan et al (2005) reported a lower 12 month readmission rate in their intervention group than in controls (66% vs. 73%,  $p = .045$ ) however this compares with 54.1% in the intervention group and 56.3% in the control group of the current study. In the first British study (Blue, Lang, McMurray et al, 2001), the 3-month rate of death or readmission for heart failure was approximately 20% in the intervention group and 33% in the control group, compared with 20% in both groups in the current study. Such findings indicate that although there was no significant difference between the intervention and control groups in this study, outcomes for the control group were on a par with the intervention group of several other studies that have reported beneficial effects. By aiming to improve upon high quality standard care, the current study was setting itself a more difficult target than most other heart failure intervention studies.

This interpretation gains some support from the comments of Cleland et al (2007) regarding the non-significant findings of the COACH study (Jaarsma et al, 2004), in apparent contradiction of many previous findings of disease management programmes

(McAlister et al, 2004). The COACH study is a large randomised controlled trial, conducted over 18 months, which compared standard care (4 appointments with a cardiologist) with a basic programme (standard care plus 9 nurse contacts) and an intensive programme (standard care plus 22 nurse contacts) for patients admitted to hospital with heart failure. Recently reported findings indicated that there were no significant differences in hospitalisation or mortality between the intervention and control groups. Cleland, Coletta & Clark (2007) suggested one explanation for this finding may be the high standard of usual care, making it difficult to find an effect. A study that did find benefits over and above optimised inpatient care was reported by McDonald, Ledwidge, Cahill et al (2002). However, the control group in that study did not receive regular follow-up by a cardiologist which may explain the difference in effect between the studies. The findings of the COACH study have not yet been published and the findings reported here are taken from a conference presentation therefore a more detailed examination of possible explanations for these findings awaits study publication.

Approaches to improve outcomes for heart failure patients must ensure that patients receive clinical care that meets with recommended guidelines. Therefore the challenge is to develop interventions that improve on good clinical care. In spite of improvements in outcomes for patients with heart failure over recent years, prognosis remains poor and ways to improve on current care are an important objective. The current study can be seen in terms of this more challenging goal. The following sections will discuss in more detail factors that may help to explain the outcomes of hospitalisation and mortality in this study.

The limitations of hospitalisation and in particular the duration of hospital admission as an outcome measure must however be recognised. Duration of hospital stay is clearly influenced by factors outside those which could potentially be influenced by the

intervention. For example, duration of hospital stay may be influenced not only by illness severity but by factors such as hospital procedures and social factors such as whether the patient has someone at home who can help to care for them. However, these outcomes were chosen because they are the outcomes which are most commonly assessed in other heart failure intervention studies and therefore were necessary to enable comparison of the intervention in this study with other studies in the field.

#### **11.4.1 The role of self-management behaviour**

It had been hypothesised that patients in the intervention group would report better performance of recommended self-management behaviours than patients in the control group. This hypothesis was mostly supported in the short-term, in that the intervention group reported more frequent performance of several of the self-management behaviours. This is an important finding as behaviour change is a key outcome of self-management interventions (Newman et al, 2004). Significant differences between the groups were found in eating a diet low in salt, keeping within guidelines for fluid intake, self-monitoring by daily weighing and checking ankles for signs of oedema. Both intervention and control groups in this study reported high levels of adherence to medication. Whilst shortcomings in self-reported assessment of adherence are acknowledged (DiMatteo, 2004) if the patients did provide fairly accurate reports, there would have been little room for improving medication adherence.

Some of the self-management behaviours were performed more often than others, for example at 6-8 weeks, 43% of the intervention group reported keeping to a low salt diet whereas 86% self-monitored for signs of oedema. Variation in practice of different self-management behaviours was also seen in the control group and has also been

reported elsewhere (van der Wal et al, 2006). It is not unexpected that dietary change should be more difficult to make and maintain than simply checking ankles for signs of oedema but this variation highlights areas where a heart failure self-management intervention may need to adopt additional measures to facilitate change in some behaviours.

It is disappointing that the significant impact on behaviour found at the 6-8 week assessment did not translate into an overall reduction in events. There are a few possible reasons why this did not occur. First of all, it must be recognised that performance of the recommended self-management behaviours will not necessarily reduce the occurrence of events in all patients. Heart failure is a serious illness and the underlying disease process will inevitably influence outcomes and this may occur regardless of patients' actions.

The relationship between self-management behaviours and health outcomes is complex and other studies have shown that improvements in behaviours do not necessarily explain health outcomes following a self-management intervention (Lorig, Seleznick, Lubeck et al, 1989). A review of self-management interventions in asthma, arthritis and diabetes found that some interventions achieved behaviour change in the absence of change in clinical outcomes while others found improvement in clinical outcomes in the absence of behaviour change (Newman et al, 2004). Clearly this relationship requires further examination.

Although previous research has identified shortcomings in the performance of heart failure self-management behaviours to be a predictor of poorer outcomes (see Chapter 2), the strength of the relationship between frequency of performance of the recommended self-management behaviours and hospitalisation and mortality outcomes is unclear. Studies in heart failure have examined self-management

behaviour and factors that influence performance of self-management behaviours (see Chapter 3) but few have prospectively examined the relationship between self-management behaviours and outcomes. The behaviours recommended in heart failure guidelines are included based on clinical consensus rather than controlled trials and have been inferred from retrospective examination of precipitants of hospitalisation (see Chapter 2).

It must therefore be borne in mind that changes in behaviour will not necessarily translate into health benefits. Reports of keeping to a low salt diet and within fluid guidelines were not related to hospitalisation and mortality outcomes in this study. A recent study (Travers, O'Loughlin, Murphy et al 2007) questioned the routine application of fluid restriction in heart failure. They found that fluid restriction in patients admitted to hospital with heart failure did not reduce the time to achieving clinical stability. This would appear to support the findings of the current study in which adhering to fluid guidelines was not associated with outcomes.

The systematic review reported in Chapter 3 found that few interventions assessed self-management behaviour or its relation to outcomes. One study that had (Jaarsma et al, 1999) reported better performance of self-management behaviours in the intervention group than the control group at 1 month and 3 months post intervention but this was not maintained at the 9 month assessment. The study did not find a significant difference between the groups in hospital admissions at 1, 3 or 9 months. Since the commencement of the current study, a further 15 published studies have been identified that directly targeted behaviour change in heart failure as an important focus of their intervention (Krumholz, Amatruda, Smith et al 2002; Kuehneman, Saulsbury, Splett & Chapman, 2002; Laramie, Levinsky, Sargent et al, 2003; Miche, Herrmann, Wirtz et al, 2003; Wright, Walsh, Ingley et al, 2003; DeWalt, Pignone, Malone et al 2004, DeWalt, Malone, Bryant et al, 2006; Sethares & Elliott, 2004; Arcand et al 2005;

Caldwell, Peters & Dracup 2005; Dunbar, Clark, Deaton et al 2005; Gwadry-Sridhar, Arnold, Zhang et al 2005; Koelling, Johnson, Cody & Aaronson, 2005; Shively, Kodiath, Smith et al 2005; Kutzleb & Reiner, 2006; Rucker-Whitaker, Flynn, Kravitz et al 2006). However, the criticisms outlined in the systematic review in Chapter 3 still apply, in that most did not assess behaviour. Others that did assess behaviour did not necessarily assess the impact of the intervention on hospitalisation and mortality. It is therefore not always possible to identify the mechanisms of action or to make a comparison between their findings and those of the current study. Two exceptions were studies by Laramee, Levinsky, Sargent et al (2003) and Wright, Walsh, Ingley et al (2003).

Laramee et al (2003) evaluated a case management intervention that incorporated discharge planning and coordination of input from multidisciplinary services, followed by an education programme after discharge from hospital. The intervention group reported better performance of self-management behaviours than the control group at 4 weeks and 12 weeks following hospital discharge, with the exception of medication adherence at 4 weeks, which was very high in both groups. Better performance in the intervention group at both timepoints was reported in daily weight monitoring, monitoring for signs of oedema, and following guidelines for fluid and salt intake. However, this did not translate into fewer hospital admissions over 90 days, which did not differ between the intervention and control groups.

Wright et al (2003) examined the outcomes of participants in an intervention by comparing those who adopted the recommended self-management strategies with those who did not. The study did not find any significant difference between the intervention and control groups in the combined outcome of death or hospital readmission (reported in Doughty, Wright, Pearl et al 2002). Patients in the intervention group received a diary to aid self-management and Wright et al (2003) compared patients who used the diary with those who did not. Those who used the diary had



lower mortality and a longer event-free survival time. Wright et al also compared intervention patients who self-monitored their weight with those who did not. Patients who did not weigh themselves had more hospital admissions and a shorter event-free survival time.

McMurray & Pfeffer (2005) have commented that self-monitoring by daily weighing seems crude, however the current study also found a relationship between daily weighing and mortality, but only in univariate analysis; it was not significant in multivariate analysis when age was included. Unlike the current study, Wright et al (2003) did not find any relationship between weight monitoring and age. However this relationship was found by van der Wal et al (2006). Possible explanations for this relationship could include greater physical disability making it difficult to weigh (as suggested by Jaarsma et al (2000) or older patients holding different beliefs about weight monitoring that make them less likely to perform this behaviour. The current study has not established the most likely reason for the relationship but it suggests that further exploration may be helpful.

Duration of weekly exercise at the 6-8 week assessment was associated with the risk of all cause hospitalisation and mortality in univariate analysis. The benefits of exercise for heart failure patients has been shown in other studies (McKelvie et al, 1995) so if a greater improvement in exercise duration had been achieved, it may have translated into a benefit on other outcomes.

Performance of self-management behaviours may have failed to translate into an impact on outcomes because they were not maintained for long enough. Significant group differences existed at 6-8 weeks but the groups no longer differed significantly at 12 months, except on checking their weight (Table 9.2). It is not known how quickly performance of the behaviours diminished after the 6-8 week assessment and a further

assessment at, say 6 months, could have been illuminating. Further assessments were not requested, however, in order to avoid placing too heavy a burden on mostly elderly patients.

Failure to maintain effects over time is a recognised shortcoming of self-management interventions (Newman et al, 2004). Consideration of ways in which this intervention could have resulted in longer-term maintenance of behaviour change is therefore important. It may be unreasonable to assume that a brief intervention which was delivered over a period of approximately two weeks could achieve changes that would last for at least a year. The addition of one or more booster sessions may have helped to overcome this problem and could have been easily incorporated into this intervention with additional telephone follow-up. This does nevertheless raise the issue of the intervention becoming more intensive.

The relationship between self-management behaviours and hospitalisation in this study is difficult to tease out because while poorer self-management may lead to an event, the occurrence of an event may impact on the practice of self-management behaviours. This process could not be examined because information about practice of self-management behaviours was collected at only two follow-up assessments approximately 10 months apart. It would be interesting to examine how patients responded to intervening hospital admissions and how their self-management behaviour was influenced.

There may have been some limitations to the measurement of behaviour which concealed some important effects. For example, patients in both intervention and control groups in this study reported high adherence to medication. However, adherence was assessed using a questionnaire, which may have been unable to detect some barriers to adherence. A questionnaire may detect instances of intentional

non-adherence where patients choose to report them or patients may acknowledge that they sometimes forget to take medication. However, a questionnaire may be less likely to identify unintentional non-adherence i.e. instances of which patients are genuinely unaware. For example, a difficulty that patients with heart failure are likely to have in taking medication as prescribed is confusion arising from a complex medication regime (Cline, Bjorck-Linne, Israelsson et al 1999). Cognitive decline, which has been found to be common in heart failure, may contribute to this problem (Almeida & Flicker 2001). Accordingly patients may believe themselves to be taking medication as prescribed when this is not necessarily the case. For example, Cline et al (1999) found patients who were taking medication that should have been discontinued.

Other heart failure intervention studies have also reported very high rates of self-reported medication adherence in both the intervention and control groups (e.g. Laramie et al 2003, Jaarsma et al 1999). A study by Bohachick, Burke, Sereika et al (2002) measured adherence using MEMS and found lower rates of adherence than had been reported in these studies. This suggests that alternative methods of assessing medication adherence in heart failure may be necessary, although all approaches have their limitations (DiMatteo, 2004). One method would be to ask patients to bring their medication to the assessment session and to explain to the researcher exactly how much of each medication they take and when. The researcher could then compare this with the prescription.

Factors which were hypothesised to be important influences on behaviour in this intervention were self-efficacy and medication and illness beliefs. It may be that a greater impact on behaviour and overall outcomes could have been achieved through a greater impact on these variables. This will be discussed in the following sections.

### **11.4.2 The role of self-efficacy**

It had been hypothesised that following the intervention, patients in the intervention group would report greater self-efficacy in their ability to manage their heart failure than patients in the control group. This was supported to some extent in that self-efficacy to follow a low salt diet and to keep within fluid guidelines improved between baseline and 6-8 weeks however these were not maintained over time. Significant differences between the intervention and control groups were also found on these behaviours. The significant relationships found between baseline self-efficacy and the practise of some of the specific self-management behaviours at the 6-8 week follow-up (Table 10.7) suggest that greater success in changing self-efficacy may have led to greater effects on behaviour. A study by Joeke, van Elderen & Schreurs (2007) assessed the relationship between self-efficacy in relationship to self-management in cardiac patients, which included 41 patients with a diagnosis of heart failure. They found that self-efficacy was related to self-management behaviour in cross-sectional analysis, however, baseline self-efficacy did not predict self-management behaviour 3 months later. The study did not report the changes over time in self-efficacy and self-management, which may have helped to clarify this relationship.

It may be the case that the behaviours were adopted for a short time but if patients did not experience benefits, self-efficacy remained unchanged and performance of the behaviours began to tail off. Lenker, Lorig & Gallagher (1984) found that improvements in health status were associated more with increased self-efficacy than adoption of health behaviours and it may be the case that this study failed to achieve overall benefits because it did not sufficiently enhance self-efficacy. The relationship between these variables is thought to operate as one of ongoing feedback and change. Examination of this process was not possible given the limited number of follow-up assessments in the study, however examination of this process is probably very limited

in any study. There remains a need for more studies that use statistical modelling to gain a better understanding of this relationship.

It may be the case that if greater change in self-efficacy had been achieved, this would have been reflected in a greater impact on behaviour and perhaps longer term maintenance of the behaviours. An important factor in increasing self-efficacy is mastery over the behaviours concerned (Bandura, 2000). To help enhance mastery, self-management interventions often include formal goal-setting by patients in which the patients choose the goals (although limited to the behaviours addressed by the intervention) and write contracts for the completion of the goals. In this intervention, the aim was to encourage patients to adopt all the intervention behaviours, rather than patients choosing which goals to follow, however patients were actively involved in deciding how to implement these behaviours. Formal goal-setting by patients was not included because of the timing of the intervention and the small number of sessions involved. Many of the patients were newly diagnosed with heart failure during the index hospital admission and therefore had no prior experience of trying to manage the illness at home other than the recent episode which had led to their hospitalisation. Even patients with a longer standing diagnosis could not be expected to know how they would feel in the early stages of recovery from the current episode. For example, it would have been difficult to set realistic goals around physical activity at such an early stage. Formal goal-setting was therefore considered inappropriate at that stage before patients had adequate experience of living with the illness and identifying where they experienced difficulties in their self-management. If the intervention had included more sessions over a longer time period, formal goal-setting and contracting could have been included.

Vicarious learning is another important factor in improving self-efficacy, for example by modelling the successful behaviour of a person with whom one identifies. While the

nurse could introduce examples of techniques that other patients have found helpful, vicarious learning is likely to occur more successfully in a group format. This method of delivering the intervention was not available in the in-patient setting where only one or two eligible patients may have been in hospital at the same time.

Although self-efficacy did not predict admission to hospital, an interesting finding was the relationship between baseline self-efficacy and mortality. In multivariate analysis, higher baseline self-efficacy to 'do all the things necessary to manage heart failure on a regular basis' was associated with a lower risk of mortality in the full sample studied, although it is recognised that the overall predictive power of the model was quite small. The only other significant predictor in the multivariate analysis was age. Other research that has examined predictors of mortality in heart failure has focused on demographic and clinical factors and, not surprisingly, has found older age to be among the strongest predictors (e.g. Cowie, Fox, Wood et al 2002; Pocock, Wang, Pfeffer et al 2006). A study by Bouvy, Heerdink, Leufkens et al (2003) reported predictors of mortality in 10 studies, which showed considerable variation in the predictor variables assessed and also inconsistency in the significance of different variables. Other significant predictors of mortality reported by Cowie et al (2002) were NYHA class and serum creatinine level but neither of these were significant univariate predictors in the current study (Table 10.1). Pocock et al (2006) found that in addition to age, a diagnosis of diabetes and lower left ventricular ejection fraction (LVEF) were the most powerful predictors of mortality. The current study used the echocardiographic assessment of global function, rather than LVEF, as a measure of systolic function and found that contrary to Pocock et al's findings, both this variable and diabetes did not predict mortality.

Heart failure is a major cause of death and understanding what factors relate to mortality is an important area for research, both to identify patients who may benefit

from additional input and to inform the development of interventions. The finding that self-efficacy may predict mortality could be an important addition to this research. This relationship has also been found in another study. Rohrbaugh, Shoham, Coyne et al (2004) found that patients' self-efficacy to perform self-management behaviours was associated with survival over the following 4 years. Kempen, Sanderma, Miedema et al (2000) found that self-efficacy predicted functional decline in the 8 weeks after diagnosis of heart failure but they did not examine the relationship with hospitalisation and mortality. The mechanism(s) by which self-efficacy may influence mortality are as yet unknown and the intervention reported in the current study did not succeed in improving the aspect of self-efficacy that was related to mortality, but these findings suggest that this is an important area to pursue in future research.

#### **11.4.3 The role of illness and medication beliefs**

Other variables that were expected to have an influence on outcomes were the beliefs patients held about their illness and medication. The intervention had little impact on patients' beliefs about their illness or medication. Both groups reported less belief in cure/control at the 12-month follow-up however there was not a significant difference between the groups. The perceived duration of the illness (IPQ Timeline) increased in the intervention group but again there was no significant difference between the groups.

According to self-regulatory theory, patients' beliefs about their illness should influence how they respond to it, which will also affect outcomes (Leventhal et al, 1984). There were some significant relationships between baseline beliefs and self-management behaviours at 6-8 weeks but only perceived timeline was a significant predictor of one of the self-management behaviours (self-monitoring for signs of oedema) in multivariate analysis. Self-reported adherence to medication was very high in both the intervention and control groups so it was not possible to evaluate the importance of

medication beliefs. If more variability in adherence was found in another study, addressing medication beliefs may be an important factor in improving adherence (Horne & Weinman, 1999).

The self-regulatory model (Leventhal et al, 1984) proposes that illness beliefs indirectly affect health outcomes through their impact on coping strategies (which would include self-management behaviours) but others have also examined the direct relationship between illness beliefs and health outcomes (Hagger & Orbell 2003). The current study found that Illness Identity was a significant predictor of admission to hospital (Table 10.1), but only in univariate analysis. A stronger belief in cure/control at baseline was related to a longer event-free survival, but again this was only significant in univariate analysis (Table 10.1). The current study was not designed as an evaluation of the self-regulatory model and may not have sufficient power to identify these inter-relationships therefore the low predictive value of these variables can not be taken as evidence that the model is inadequate. The significant relationships that were found indicate that this may be an interesting area for further study. Although many studies have examined the relationship between illness beliefs and health outcomes, the outcomes chosen are usually quality of life, psychological well-being and self-reported physical function. Of the 45 studies reviewed by Hagger & Orbell (2003), none examined the relationship between illness beliefs and hospitalisation or mortality. Further examination of these relationships would possibly add to the value of the theory.

An important issue to examine is whether this study assessed and targeted the most salient beliefs in heart failure. Very few studies have examined patients' beliefs about heart failure and a better understanding of this area may help in the future development of self-management interventions.



#### **11.4.4 The role of mood**

It is perhaps surprising that depression at baseline did not predict outcome as this variable has been found to predict outcome in other studies (Jiang et al; 2001, Junger et al, 2005). A possible explanation for the relationship between mood and outcomes being weaker than expected is that patients with severe psychiatric disorders were excluded from the study thereby reducing the variance in scores on measures of mood. However, the percentage of patients with a depression score in the clinical range (HADS score  $\geq 8$ ) was very similar to that reported by Junger et al (2005), who found that 30.1% of patients had a depression score within the clinical range on the HADS, compared with 31.1% in the current study (Table 6.5). Depression was however a significant predictor of shorter exercise duration in univariate analysis, concurring with the findings of van der Wal et al (2006). This suggests that addressing mood is still an important issue to consider in order to optimise the benefits of self-management interventions in heart failure.

The question nonetheless remains as to whether directly addressing mood would have improved the outcomes of this intervention. There is some related evidence in coronary heart disease that suggests that this approach may not lead to improvement in other outcomes. The Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomized Trial (Berkman et al, 2003) examined whether mortality and recurrent MI were reduced by treatment of depression and low perceived social support. Although improvements in depression and perceived social support were found, these did not translate into improvements in event-free survival.

#### **11.4.5 The importance of comorbidity**

Analysis of predictors of outcome found that one of the most consistent baseline predictors of outcome were the number of comorbid illnesses. It is important that

comorbidity increased the risk not only of all cause events but also heart failure events. Approximately 70% of the study sample had at least one non-cardiac co-morbidity and these could have contributed to many readmissions. McMurray & Stewart (2002) found a similar level, with 65% of patients hospitalised with heart failure having at least one major co-morbidity. The risk of hospitalisation among people with heart failure has been found to increase with the number of non-cardiac comorbidities (Braunstein, Anderson, Gerstenblith et al 2003). The intervention in the current study was brief and focussed on self-management of heart failure. Perhaps in an elderly population with such a high prevalence of co-morbid illness, it is unrealistic to target a single disease. The Expert Patient Programme (Department of Health, 2001), based on the Chronic Disease Self-Management Programme (Lorig et al, 1999) takes this approach and instead welcomes people with any chronic illness to attend a generic group self-management programme. A recent randomised controlled trial of this programme (Kennedy, Reeves, Bower et al, 2007) included 629 patients with a wide range of long-term conditions, although it is not known if any had heart failure. The study found that at the 6-month follow-up, the intervention group reported greater self-efficacy, more energy, better psychological well-being, less health distress and less limitation in social roles than the control group. However there were no differences between the groups in the number of health care visits, self-reported general health or pain. A drawback of this programme is that participants receive no disease-specific information – the programme concentrates on teaching generic self-management skills such as problem-solving which they can then apply to all aspects of their lives. Patients with heart failure, like patients with other chronic illnesses, need to know how to manage the specific demands of their illness as well as learning generic skills, so would need additional input over and above the Expert Patient Programme. The issue of how best to develop self-management interventions that deal with the demands of both a specific disease and one or more co-morbid illnesses remains unresolved and is an important area for further research.

## **11.5 Intervention efficacy – quality of life and mood**

The sections above discuss the efficacy of the intervention on hospitalisation and mortality and possible explanations for the findings. Other study outcomes included the secondary outcomes of quality of life and mood. These are important outcomes since it is crucial not only to reduce hospitalisation and mortality but to do so without having a detrimental impact on patients' quality of life and psychological well-being. On the contrary, it would be expected that a self-management intervention which helped to enhance patients' ability to manage their illness would improve their quality of life.

It had been hypothesised that patients in the intervention group would report better quality of life and mood than the standard care control group at 6-8 weeks and 12 months following discharge from the index admission. Patients in the intervention group reported significant improvement in mental quality of life over the study period whereas those in the control group did not (Tables 8.3 and 8.4), however the differences between the groups at 6-8 weeks and 12 months were not statistically significant. It is nevertheless encouraging that an intervention which required patients to pay closer attention to their illness did not have a detrimental effect on their mental quality of life but, on the contrary, may have conferred some benefit. In contrast, physical quality life, assessed by the SF-36, was not influenced by the intervention and neither did it change over time for the whole sample.

Few other heart failure intervention studies have evaluated generic health-related quality of life as an outcome. Seven randomised controlled trials were identified that assessed quality of life using the SF-36 (Stewart et al, 1999; Harrison et al, 2002; Dunagan et al, 2005; Martensson, Stromberg, Dahlstrom et al, 2005; Shively et al, 2005; Smith, Forkner, Zaslow et al, 2005; Thompson, Roebuck & Stewart, 2005). Of these, 4 studies found no effect of the intervention on either physical or mental quality

of life (Harrison et al, 2002; Shively et al, 2005; Smith et al, 2005; Thompson, Roebuck & Stewart, 2005). The remaining 3 studies found a significant impact on physical, but not mental quality of life (Stewart et al, 1999; Dunagan et al, 2005; Martensson et al, 2005), however, only in the study by Martensson et al (2005) were the effects maintained up to 12 months. It is possible that studies that found benefits on physical quality of life are ones which, in contrast to the current study, had also found an impact on hospital admissions. However, examination of these studies indicated that this was not necessarily the case. Only 4 of these studies had also evaluated admission to hospital so it is not possible to draw any conclusions about the relationship between reductions in hospital admission and improvements in physical quality of life. Stewart et al (1999), Dunagan et al (2005) and Thompson, Roebuck & Stewart (2005) all reported reductions in hospital admissions but the latter study did not find an effect on quality of life. Harrison et al (2002) did not find an effect on either outcome.

It would appear to be the case that physical quality of life as assessed by the SF-36 is difficult to change in heart failure. Although better delivery of care through disease management programmes may improve health outcomes in some studies, changes in care do not necessarily impact on physical quality of life, other than in the short term. Heart failure is a serious and chronic illness therefore its impact on aspects of physical quality of life, such as patients' perceptions of their general health and performance of life roles, may remain unchanged even when symptoms improve. This may help to explain why physical quality of life did not change in the current study even though disease-specific quality of life improved in the sample as a whole.

Disease specific quality of life, as measured with the MLHF, did not differ between groups but there was a significant improvement over time in the whole sample. Baseline reports will inevitably have been affected by patients being in hospital at that time however the improvement over the following 12 months was highly significant

( $p < .001$ ) and it is encouraging that one year further on in their illness, patients were still experiencing better heart failure specific quality of life. This may be a reflection of the early optimisation of treatment and ongoing care.

The intervention did not have an impact on patients' mood, neither did mood change over time in the sample as a whole (Tables 8.7 – 8.12). Few other heart failure interventions have assessed mood as an outcome. No randomised controlled trial was identified that used the HADS or PANAS. Dunagan et al (2005) used the Beck Depression Inventory (Beck, Ward, Mendelson et al, 1961) in an evaluation of a disease-management programme but did not find a significant effect. The intervention in the current study did not directly target mood and, therefore it may not be surprising that mood scores did not change significantly over time. Although mood was not a significant predictor of primary outcomes in the study, it is an important outcome in its own right. Incorporation of techniques that directly address anxiety and depression, which have been evaluated in post-myocardial-infarction rehabilitation (Lewin, Robertson, Cay, Irving & Campbell, 1992), may be a useful addition to heart failure self-management.

## **11.6 Efficacy of the intervention in newly diagnosed patients**

An important finding of this study was that the intervention resulted in better outcomes in the subgroup of patients who had been newly diagnosed with heart failure. Differences between newly diagnosed intervention and control group patients were already apparent at 90 days following discharge from the index admission, during which time the intervention group patients had fewer readmissions for heart failure and spent fewer days in hospital for heart failure. Over the 12-month follow-up period, fewer patients in the intervention group were admitted to hospital for heart failure and the number of heart failure admissions and the days spent in hospital for worsening heart

failure were lower in the intervention group. The percentage of patients experiencing a heart failure event i.e. the combined outcome of death or readmission for heart failure, was also lower in the intervention group. No differences were observed between the groups in all-cause events or hospital admissions. The groups did not differ significantly in 12 month mortality however the low mortality rate (4.7%) in newly diagnosed intervention group patients is noteworthy.

As this was a subgroup analysis, the findings must be treated with caution, nevertheless they highlight an important area for further study. In addition, a new diagnosis of heart failure was in itself a predictor of outcome, indicating that the period immediately following diagnosis is an important time for further intervention. Stromberg (2005) maintained that newly diagnosed patients would not be receptive to education because receipt of the diagnosis could trigger a crisis but the findings of this study suggest that such concerns are unfounded. A study by Riegel et al (2000) reported that their intervention was not effective overall but did have a beneficial effect in patients who were moderately symptomatic. Riegel et al proposed that there may be a 'window of opportunity' in which interventions to enhance self-management are most likely to have an effect. Recruitment to the current study took place when patients were in hospital and it may be the case that newly diagnosed patients and those with a longer-standing illness respond differently to a hospitalisation.

In order to identify why the intervention was effective for newly diagnosed patients but not those with established disease, analysis was performed to examine whether there were any differences between new and existing patients in changes in process variables. For example, it would seem reasonable to expect that patients who have had heart failure for some time would have developed ways of managing it and even where these are ineffective they may remain difficult to change. In contrast, newly diagnosed patients may find it easier to adopt the self-management behaviours introduced by the

nurse. However, the findings did not support this hypothesis in that self-management behaviours did not differ between the intervention and control groups by subgroup.

Another possible explanation of the findings was that the cognitions and/or mood of newly diagnosed patients were more amenable to change than those of patients with a longer standing diagnosis and that such changes influenced outcomes. This hypothesis was also unsupported by the findings in that cognitions and mood did not change differentially by study group within these subgroups.

The process(es) by which the intervention was effective in newly diagnosed patients but not those with longer-standing illness remains unexplained. It may be the case that the number of patients in this subgroup ( $n = 90$ ) provided insufficient power to detect any effects. Another possibility is that the findings may be explained by variables that were not assessed in the study. It is also possible that differences in self-reported adherence were not identified by the measurement tool used in this study. It may be the case that adherence was better in newly diagnosed patients. Those with longer-standing illness may have had several changes of medication during their illness possibly leading to greater scope for confusion whereas newly diagnosed patients were starting afresh so the intervention may have been easier to put into practice. This remains an important and interesting area for further study.

This study is probably unusual in including both newly diagnosed patients and those with longer-standing illness in a single self-management intervention. Other studies have tended to include either one or the other of these subgroups of patients, but not both. When Farmer, Wade, Goyder et al (2007) examined the effects of a self-monitoring intervention in diabetes within subgroups, they did not find any effect within a subgroup defined by duration of diabetes. However, they had defined the subgroups by median duration ( $\leq 36$  months and  $> 36$  months) rather than identifying those who were recently

diagnosed. In contrast, when Parchman, Arambula-Solomon, Noel et al (2003) examined progress through stages of change for self-management behaviours following a diabetes education programme, they found that those with diabetes for less than 2 years were significantly more likely to progress at least 1 stage of change for diet and exercise than those with diabetes for more than 2 years. This progress was significantly associated with a decline in blood glucose levels assessed by HbA1c. Neither of these studies examined effects in newly diagnosed patients however. The applicability of self-management interventions across the duration of an illness and how they may need to change to meet the needs of patients at different stages of their illness is an interesting area for further study.

## **11.7 Other considerations in interpretation of the study findings**

It is important to ask whether there are alternative explanations for the study findings. For example, the study found a positive effect of the intervention on some self-management behaviours, at least in the short term, so it is important to consider whether these findings did in fact result from the intervention or whether they can be explained by other factors. One possibility is that the difference found between the groups in self-reported performance of self-management behaviour does not reflect a real difference between the groups but is a result of a social desirability response bias (Marlowe & Crowne (1961) in the intervention group, as a consequence of having participated in a self-management intervention that they know aimed to encourage performance of these behaviours. This explanation would appear unlikely in view of the variability of response across behaviours. If patients were responding according to what they perceived were the expectations of the study, it would seem likely that they would report high performance across all behaviours that were included in the intervention. In fact, high performance of these behaviours (performance on  $\geq 6$  days in



the preceding week) varied from virtually all patients reporting taking medication as prescribed to less than half reporting eating a low salt diet.

It is also important to consider whether the differences found in self-management behaviour resulted from the problem-solving approach used or whether they were achieved simply by better provision of information about self-management to the intervention group than to the control group (Table 4.1). The findings from interventions in other chronic illnesses suggests that this is unlikely, as provision of information is not usually sufficient to achieve behaviour change. However, it would have been possible to examine this more effectively by providing the control group with the intervention booklet (Appendix B) while the intervention group received both the booklet and the nurse intervention.

Lack of a significant effect on some questionnaire measures could also come about as a result of 'response shift'. Follow-up responses to questions about constructs such as self-efficacy and quality of life may not simply reflect real changes in those constructs over time but may reflect changes in the way respondents conceptualise those constructs, in the importance they give to them and in their internal standards of measurement (Schwartz & Sprangers, 1999). So, for example, following an intervention, participants may be able to do more physically but this may not be reflected in an improvement in reported quality of life if patients' expectations of what they should be able to do have also increased. Or patients' standard of measurement of a construct such as self-efficacy may change, for example by becoming more realistic following the intervention than it had been previously. This 'down-regulation' of the internal standard of measurement may mask actual improvements. Such phenomena could also occur in the opposite direction leading to an exaggerated positive effect. It is not known if response shift contributed to any of the findings in the current study. Some studies have tested for response shift by asking people to retrospectively evaluate their

baseline status on a particular construct and to compare it with their actual baseline reports. A difference between these two measures is judged to result from response shift (Rapkin & Schwartz, 2004). Such evaluations are not routinely reported in studies in health psychology, for example a search of the journal *Health Psychology* found response shift discussed in only one article (Schwarz, 1999) while *Psychology and Health* identified two articles (Schwartz, Sprangers, Carey et al, 2004; Yardley & Dobb, 2007). When Yardley & Dobb (2007) examined scores on the SF-36 in a sample of patients with Ménière's disease, they found evidence for response shift on all scales except physical function. Such findings suggest that response shift could be an important factor to examine in evaluations of self-management interventions.

The intervention was found to have benefits in a sub-group of newly diagnosed patients. Caution has already been expressed above regarding the interpretation of sub-group findings but other possibilities for the findings must also be considered. One is that the doctors providing follow-up care did not remain blind to study group allocation as specified in the study design and differences in outcomes between the groups resulted from differences in follow-up care. This explanation is not supported by the study findings. The newly diagnosed intervention and control group patients did not differ in the number of follow-up appointments or in the prescription of heart failure medication. Furthermore, if unblinding of the doctors had led to the intervention effect, it is likely that it would have led to an effect in the whole study sample, not just those who were newly diagnosed.

When people choose to participate in a randomised controlled trial, it is possible, or even likely, that they will have a preference for one arm of the trial over the other (Brewin & Bradley, 1989) and therefore may be disappointed if they are randomised to the alternative arm. This could affect study outcomes. It would be expected that patients would only have chosen to take part in the study if they were interested in

participating in the intervention. Randomisation to the control group could have resulted in disappointment which adversely affected patients' mood or quality of life. This possibility would appear unlikely given the lack of significant group differences on these outcomes. Alternatively, disappointment at randomisation to the control group could have prompted patients to seek out more information about how they could self-manage their heart failure and make changes they would otherwise not have made, thus reducing the differences in behaviour between the groups. It is not possible to tell if this occurred in this study but the low levels of performance of some of the behaviours in the control group suggest it is unlikely. Preference trial designs (Brewin & Bradley, 1989) can be used to try to overcome the problems that randomisation to the non-preferred arm can raise but it must be borne in mind that this type of design requires a much larger study sample.

It is necessary to consider whether the failure to find significant effects on some of the secondary outcomes could have been the result of insufficient power to detect effects on these outcomes. The outcomes of quality of life and mood were analysed using ANCOVAs and repeated measure ANOVAs. To detect a moderate effect on these tests, with  $p < .05$  and power of .80, would have required sample sizes of 130 and 86 respectively. Accordingly the sample sizes of 143 at 6-8 weeks and 110 at 12 months were sufficient for the repeated measures ANOVAs over the three time-points and for the ANCOVAs at 6-8 weeks, but not 12 months. It is therefore acknowledged that the sample sizes did not meet the required numbers for some analyses at the final assessment. However, given the consistent pattern of findings, it is considered unlikely that increased numbers would have resulted in different findings.

Differential dropout between the groups is another potential confounding factor. However, completion rates of the questionnaire measures over time were similar in

both the intervention and control groups so this cannot be seen as contributing to the non-significant findings in the study.

### **11.8 Suggestions to improve the efficacy of the self-management intervention**

One question in all studies that develop and apply self-management interventions is whether the findings and the experience of the study lead to any suggestions of how the intervention may be improved in an attempt to increase efficacy.

The intervention evaluated in this study produced significant improvements in some aspects of self-management behaviour and self-efficacy and also showed benefit in a subgroup of newly diagnosed patients. It is important to consider ways in which these effects could have been strengthened so that they may have translated into an overall impact on the primary outcomes.

A key factor to consider is the brevity of this intervention. The non-significant outcomes of such an intensive intervention as the COACH study (Jaarsma et al, 2004) serve to highlight the scale of the challenge for this brief self-management intervention to produce a reduction in hospital admissions. The current study had aimed to design a brief intervention that would be low in cost and could be delivered within the staffing resources available to most hospitals. The self-management intervention was briefer than most other interventions that have been evaluated in heart failure which may explain the non-significant findings. Although the study by Stewart et al (1999) had consisted of only a single home visit, the intervention also allowed for referral to other services of patients who were showing signs of deterioration at the home visit. Stewart & Horowitz (2002) reported that 26% of patients received additional home support services but the intensity of this additional care was not reported. Such additional care may have made a significant contribution to overall outcomes. The study by Koelling et

al (2005) evaluated a single intervention session, however it has been highlighted above that the benefits achieved may have been possible only because of the poor outcomes in the control group. Varma et al (1999) also reported significant benefit following a single education session (although reporting was unclear) however, this was also in comparison to very poor outcomes in the control group with 66% readmitted for heart failure over the 12 month follow-up period.

An important point to consider therefore is whether a more intensive self-management intervention would result in improved outcomes. One or more extra sessions could have been used to include additional strategies to enhance self-efficacy for self-management behaviours (see section 11.4.1). Maintenance of performance of self-management behaviours could have been addressed by the inclusion of additional booster sessions. Exercise emerged as a potentially important variable and the inclusion of extra sessions could have allowed a greater emphasis on overcoming barriers to increasing physical activity. When Lorig, Gonzalez, Laurent et al (1998) compared a 3 week programme for arthritis with their standard 6 week programme, they found that the more intensive programme achieved better results. A recent review of diabetes self-management interventions (Glazier, Bajcar, Kennie & Willson, 2006) also suggested that more intensive programmes may achieve better outcomes, although not all the studies included in the review evaluated self-management interventions. Nevertheless, research in other chronic illnesses has not identified an optimal intervention intensity (Newman et al 2004).

One option to consider is additional sessions to be delivered on an out-patient basis or in the community. These sessions could be delivered on a group basis which would have the advantage of containing costs and would also confer the benefits of meeting as a group, for example, a greater opportunity to enhance self-efficacy (see section 11.4.2). A group programme could also be made available on a wider basis to patients

who have been diagnosed with heart failure but have not necessarily been admitted to hospital. There is some indication that rehabilitation programmes are being introduced into heart failure management (e.g. Austin, Williams, Ross et al 2005) and this type of programme could readily be adapted to incorporate self-management principles. The optimal intensity for such an intervention remains a question for future research.

Another important issue to consider is treatment fidelity (Bellg, Borrelli, Resnick et al 2004), that is, the extent to which the intervention was delivered as intended. It is a possibility that the lack of an overall effect of the intervention resulted from it not being delivered as intended. Delivering a self-management intervention was new to the nurse involved in this study therefore the study involved a learning period. Evaluation of the nurse's development was made through role play in training sessions, one of which was video-recorded. Further evaluation could have been made by observing or tape-recording the nurse in practice, delivering the intervention to one or more patients. This would have brought attention to any areas which could have been improved, for example if the nurse was inclined to revert to a didactic approach. This type of evaluation was not incorporated due to practical constraints but would now be considered an important aspect of training and would be included as an ongoing feature of any future nurse training. Ensuring that treatment fidelity is satisfactory provides greater confidence that lack of an effect can be attributed to the content of the intervention, rather than the way it is implemented.

This study also raises an important question about what are the minimum criteria for a self-management intervention. An examination of the literature on self-management in other chronic diseases identifies considerable variation in their content. Some, particularly in diabetes and arthritis, are intensive interventions that target a range of areas, including behaviours, cognitions and mood (Newman et al 2004). Many teach skills such as problem-solving and goal-setting which Lorig & Holman (2003) contend

are key self-management skills. Definitions of self-management such as that given by Barlow et al (2002) imply that interventions should address self-management of the medical and emotional aspects of the illness and the changes in life roles that are required. The intervention which has formed the subject of this thesis focussed on improving self-management of medical aspects of heart failure.

It might be argued that an intervention that does not address all of these aspects of self-management does not conform to a biopsychosocial approach (Engel, 1977). However, minimising unplanned hospital admissions, a primary aim of the current intervention, is not a purely biological outcome but clearly has psychological and social significance as well as behavioural antecedents. The intervention was delivered on an individual basis and accordingly those issues which a patient identified as most important for managing his/her heart failure, including psychological and social issues, could be addressed using the problem-solving approach. Nevertheless, the inclusion of a period of preliminary qualitative research in the development phase of the intervention, which had not been undertaken due to time constraints, may have uncovered other outcomes which patients considered important to address. While steps to help prevent rapid deterioration in patients' health (and thus avoid unplanned hospital admissions) are an essential element of heart failure self-management, extension of the intervention to address additional aspects of heart failure self-management may have led to greater benefits.

## **11.9 Strengths of the study**

A number of factors contributed to the strength of this study.

### **11.9.1 Quality of standard care**

The design of this study improved upon many other interventions that have been developed in heart failure in that it compared the intervention to a control group who received optimised medical care. In contrast, many other heart failure interventions have compared an intervention group who received optimised care with a control group who did not. The design of the current study means that any effects found are over and above those achieved through optimised medical care.

### **11.9.2 Blinding**

Another strength of this study was that the cardiologists who delivered patient care were blind to study group allocation. This is another important way in which the study has improved on the design of most other studies of heart failure interventions. In studies where the cardiologists were not blind, it is possible that the cardiology care received by the intervention and control groups could have differed. Where this type of intervention is delivered by a heart failure nurse, consultation with the cardiology team is likely to remain an essential part of the nurse's practice therefore blinding can be difficult. Nevertheless, if the benefit of this type of intervention is to be evaluated properly it is essential that the only differences in care between the intervention and control groups are as stated in the intervention description.

### **11.9.3 Intention to treat analysis**

The study used intention-to-treat analysis, which includes the outcomes of all patients recruited even if they dropped out before the end of the study. This type of analysis



helps to give a more realistic indication of the likely effectiveness of the intervention once integrated into routine care.

#### **11.9.4 Study outcomes assessed**

Another strength of this study is that it assessed a wide range of variables including clinical outcomes. The primary outcomes that are typically assessed in other heart failure studies i.e. hospital admission and mortality were also assessed in this study which is important if the intervention is to be compared with other work in the field.

Assessment of other variables such as cognition and behaviour is also important in order to gain a better understanding of how the intervention achieves any observed effects. Measurement of these variables is rare in other heart failure studies so while they may aim to improve outcomes by advising patients to adopt a number of self-management behaviours, it is not possible to tell if this aspect of the intervention has had any impact. The wider range of variables assessed in this study has helped to identify some factors that are important for this type of intervention to address.

The current study is somewhat unusual in health psychology research in having clinical events as its primary outcome. Michie & Abraham (2004) argue that where an intervention is targeted at changing behaviour then behavioural outcomes are likely to prove the most informative when considering whether such an intervention works. In the current study, the intervention did have a significant effect on behaviour, providing evidence of its efficacy on the areas targeted. Michie & Abraham (2004) make the important point that as health status is influenced by many factors other than health behaviours, a focus on health status as an outcome could obscure effective targeting of behaviour. This point is very pertinent to the current study as the positive effect of the intervention on behaviour did not translate into an overall benefit on health outcomes and the limitations of using hospitalisation as an outcome are acknowledged.

Nevertheless, if the reason for targeting health behaviours is to improve health status, then assessment of any clinical benefit is also important. Evidence of benefit for such outcomes is likely to be necessary if self-management interventions are to be widely adopted in the health service.

#### **11.9.5 Intervention manual**

The intervention evaluated in this study was described in a manual for use by the nurse delivering the intervention (Appendix A). The development of manuals for self-management interventions is important. Journal articles do not allow for a detailed description of an intervention so a full understanding of what actually occurred can be difficult. This raises problems for making comparisons between studies that describe their interventions in similar ways but may in practice have differed in their delivery. For example, the intervention by Stewart et al (1999) referred to 'remedial counseling' which was not described in further detail. When asked about the nature of the counselling and whether any particular counselling model had been used, Stewart responded that they were 'pragmatic and eclectic' (personal communication). The intervention also referred to 'strategies designed to improve treatment adherence and response' but it is not clear what these were. The level of detail in the reporting of Stewart et al's study is by no means atypical and it can be seen that without greater precision about the content of the intervention it would be difficult to know if two interventions describing their intervention in these terms were actually similar in practice. Replication of interventions also becomes difficult if the content and process of delivery are not laid out in detail. This is not to say that a manual should act as a rigid protocol. An important aspect of delivering a self-management intervention is being able to adapt it to the needs of the participants therefore the person delivering the intervention needs to adopt a flexible approach. The manual nevertheless serves

the purpose of clarifying the techniques used and the self-management behaviours that are to be addressed.

### **11.10 Limitations of the study**

Recruitment to the study took longer than anticipated and was curtailed before the required sample size was reached. This will have reduced the power of the study to find any effect.

The duration of follow-up in this study was only 12 months therefore it is not known if any beneficial effects were maintained after this time. Failure to maintain benefits is a common short-coming of self-management interventions (Newman et al, 2004) therefore knowledge of the longer-term outcomes of this intervention would be helpful. Nevertheless, the period of follow-up is longer than for many studies in heart failure. For example the study by Blue et al (2001) reported 12 month outcomes but the intervention itself ran for the whole 12 month period, whereas in the current study the 12 month assessment time was approximately 50 weeks after the end of the intervention. When Ojeda Anguita, Delgado et al (2005) ran an intervention for an average of  $16 \pm 8$  months, they reported a lower rate of heart failure admissions and lower mortality in the intervention group during the treatment period. One year after stopping the programme, however, there was no longer any difference between the groups in these outcomes. It is therefore important when comparing the duration of effects with other studies to take this into consideration.

The intervention was delivered by one heart failure nurse. While this has the benefit of reducing inconsistencies in delivery, it is possible that there would be differences in the efficacy between health care professionals. The description of the intervention in a manual was designed to minimise such differences but it remains possible that some

health care professionals may be better than others at learning the skills needed to facilitate a self-management intervention.

Ideally, the design of the study would have involved keeping the self-management intervention completely independent of medical and nursing care. However, some confounding of self-management and nursing care were inevitable in that the nurse also performed a clinical assessment at the home visit and the clinic visits that occurred as a result of patients' contacts. Complete separation of the self-management intervention from clinical care would have required the intervention to be delivered by a person who did not have any other contact with the patients but this was not possible as additional personnel were not available. Nevertheless, it must be borne in mind that the model of delivery used in this study would facilitate the integration of self-management into standard care.

In designing the study, the timing of the second assessment was a pragmatic decision to arrange assessments to coincide with out-patient visits. We wished to carry out an early assessment to evaluate any immediate effects of the intervention but the first out-patient visits were organised for 6-8 weeks after discharge from hospital. A disadvantage of this duration was that it allowed quite a lot of time in which readmissions to hospital could occur and these admissions would be likely to impact on the variables that were being assessed.

This study was not able to monitor the impact of an admission to hospital during the follow-up period on self-management behaviours and cognitions. Rothman (2000) asserted that people have clear expectations about the outcome of a new behaviour and if these expectations are not met they will be less likely to maintain the behaviour. The study had been designed so that if deterioration triggered further contact with the nurse, this would allow for further input and reinforcement of the intervention as

necessary. Nevertheless, an admission to hospital may have led people to discontinue behaviours they had been performing previously. Examination of this self-regulatory process in greater detail would require more frequent assessments than were performed in this study. In any event, a detailed understanding of this ongoing adaptive process would probably entail more assessments than is feasible for any research study.

When the study questionnaires were being chosen, it was decided not to include a measure of self-management behaviour at baseline because it was anticipated that many patients would be newly diagnosed and would not have experience of self-managing heart failure. In retrospect perhaps these behaviours should have been examined anyway, allowing for the fact that they would not have applied to some patients. A proportion of newly diagnosed patients may have been engaging in some of the behaviours to manage other cardiac conditions. A baseline measure would have the advantage of enabling assessment of change over time and examination of any correlation between change in process variables and change in behaviours. More detailed assessment of salt and fluid intake could also have been made which would have enabled examination of any relationship between intake levels and clinical outcomes. The measurement of behaviour could also have been improved by taking additional steps to establish the psychometric properties of the measure in line with recommended good practice (DeVellis, 2003). Internal consistency had been assessed but was not high, which was expected as self-management behaviours are not necessarily highly correlated with each other (Glasgow et al, 1989). Additional tests could have been performed, for example, test - re-test reliability could have been established by preliminary piloting of the measure on two or more occasions within a brief timeframe. Construct validity could have been assessed by comparing the reported findings for physical activity with another measure such as a 6-minute walk test, a widely used measure of physical function in healthcare settings or responses for

individual behaviours on this scale could have been compared with other scales that assess behaviours such as exercise, diet and medication adherence. These tests were not undertaken because of time constraints in the development phase but this is recognised as a study limitation.

Understanding of the relationship between psychological factors, behaviours and health outcomes is not well developed in heart failure and requires further exploration. For this reason, a period of exploratory research prior to the development of the intervention would have been helpful however this was not feasible within the financial and time constraints of the study. Without the benefit of such research at the inception of this study, pragmatic decisions had to be made about how best to proceed on some matters, making use of what was considered to be the most relevant research from other chronic illnesses. This follows the path by which many self-management interventions have been developed, drawing on existing theory and clinical opinion and working within the constraints of the clinical environment in which they are to be delivered. A more detailed knowledge of the behaviours, cognitions and emotions that are related to outcomes in heart failure should greatly enhance the development of future interventions.

### **11.11 Conclusions and recommendations for further research**

The aims of this study were to design a self-management intervention for people admitted to hospital with heart failure, to describe the intervention in detail in a manual and to evaluate the intervention in a randomised controlled trial. These aims were achieved and, to my knowledge, this is the first study of a self-management intervention for heart failure to be conducted in the UK.

The intervention had a significant impact on some aspects of self-management behaviour and although the intervention did not have a significant overall effect on the primary outcome of hospital admissions, subgroup analysis suggested that the intervention was successful in reducing hospital admissions for heart failure in newly diagnosed patients.

This study has identified several areas which could benefit from further research. A greater understanding of the relationship between psychological factors, behaviours and health outcomes would be of benefit in the design of future interventions. This area is not well developed in heart failure and requires further examination.

This study found that exercise duration and weight monitoring were related to outcomes but the relationships, although significant in univariate analysis, were no longer significant in multivariate analyses. Possible explanations include inadequate measurement of behaviour in this study, lack of power to detect effects or absence of a strong relationship between these behaviours and the outcomes of hospital admissions and mortality. A better understanding of the nature of this relationship has important implications for the development of clinical guidelines for heart failure and the content of future self-management interventions.

Self-efficacy proved to be a potentially important predictor of mortality in heart failure. Further exploration of this relationship and ways to enhance patients' self-efficacy to manage their illness may provide a valuable contribution to improving outcomes in heart failure.

The study findings suggest that the period shortly after diagnosis is an important time for intervention in heart failure. Contrary to the views of Stromberg (2005), this study has shown that newly diagnosed patients may be particularly receptive to a self-

management intervention. Although further research is needed to confirm the findings, this has clear implications for the incorporation of self-management interventions into clinical practice. When heart failure is first diagnosed on admission to hospital, the period shortly before and after discharge would appear to offer a key time for introducing a self-management intervention. It is important to explore how self-management interventions could be adapted and their benefits evaluated for people who are first diagnosed with heart failure as out-patients or in primary care.

Further research is needed to examine ways in which the benefits seen in newly diagnosed patients can be enhanced. Two issues appear of particular importance. It is necessary to explore ways to extend the benefits seen for newly diagnosed patients to those already diagnosed with heart failure and it is also important to try to reduce all-cause admissions to hospital, not only admissions for heart failure.

It may be the case that patients would benefit from a more intensive intervention. The current intervention was very brief and it may have been overly ambitious to expect to achieve a significant overall benefit with an intervention of such low intensity. One option to consider is additional sessions to be delivered on an out-patient basis or in the community. These sessions could be delivered on a group basis which would have the advantage of containing costs and would also confer the benefits of meeting as a group, for example, a greater opportunity to enhance self-efficacy (see section 11.4.2.). There is some indication that rehabilitation programmes are being introduced into heart failure management (e.g. Austin et al, 2005) and this type of programme could readily be adapted to incorporate self-management principles. Exploring the possible benefits of extending the intervention in these ways is an important area for future study.

In newly diagnosed patients, the intervention was successful in reducing hospital admissions for heart failure but not all-cause admissions. Coupled with the finding that



comorbidity was a significant predictor of both all cause and heart failure outcomes, this suggests that further examination of how a self-management intervention for heart failure should address comorbidity is essential. The intervention in the current study was brief and focussed on self-management issues specific to heart failure. Perhaps in an elderly population with such a high prevalence of co-morbid illness, it is unrealistic to target a single disease. The issue of how best to develop self-management interventions that deal with the demands of both a specific disease and one or more co-morbid illnesses remains unresolved and is an important area for further research.

The current study has made a number of important contributions to the field of self-management in heart failure. The need to develop interventions that can help to enhance upon optimised medical care has been highlighted. A number of areas that would benefit from further research and suggestions for ways to enhance self-management interventions have been discussed. The findings of subgroup analysis have provided a fascinating hypothesis for future work in the field of heart failure self-management.

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## **APPENDIX A. INTERVENTION MANUAL**



# A nurse-led self-management programme for patients admitted to hospital with heart failure

This manual may be used only following an accompanying training course.

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## INTRODUCTION

Patients with heart failure have to follow a complex behavioural regime, which can include taking different medicines, making dietary changes, monitoring for signs of fluid retention, and taking exercise.

The aim of this intervention is to target the behaviours that patients need to adopt on a daily basis in order to:

- adhere to their recommended treatment regime
- identify any signs of worsening heart failure and take appropriate action
- take control of the behaviours associated with managing their heart failure

The programme will help patients to address any difficulties they have in making and maintaining behavioural changes. By helping to enhance patients' adherence to their recommended treatment regime, it is hoped that complications leading to unplanned hospitalisations will decrease, and patients' quality of life will improve.

Patients with heart failure also may need to give up smoking or lose weight. These are very difficult to achieve and, although they are desirable and patients who express a wish to address them will be given support, they are not seen as the main targets of this intervention. This brief intervention is not considered to be of sufficient duration to give all of these issues the attention they require. The main behaviours being addressed in this intervention are monitoring of weight,

oedema and breathlessness, adherence to medication, salt and fluid restriction and exercise.

A traditional educational approach to helping patients adopt treatment recommendations has been to provide information about what needs to be done. A consistent finding from work in chronic illness is that, although the correct information is essential to ensure that patients know what to do, it is often not sufficient to bring about behaviour change. Health care professionals will be familiar with this from their own clinical experience where patients who are very aware of the risks of smoking and obesity, for example, do not change their behaviour. A self-management approach aims to help patients identify barriers to optimal self-management and to help them identify the solutions that will work best for them.

## BEHAVIOUR CHANGE

To enable people to change their behaviours and follow the recommended treatment regimen, it is necessary to consider the barriers that can prevent them from making the required behaviour changes. Barriers to behaviour change can be physical or psychological and problem-solving skills can be used to help overcome these barriers.

Individuals' beliefs about their illness and treatment may raise psychological barriers to how they deal with it. During the intervention, unhelpful beliefs will be challenged and beliefs that enhance self-management will be encouraged.

Important beliefs are:

- The patient has an important role to play in managing their condition
- Performing the required behaviours will have a beneficial effect
- The patient has the ability to perform the necessary behaviour (self-efficacy)

By tackling unhelpful beliefs and adopting a problem-solving approach, the programme aims to equip patients with the ability to overcome barriers to following their treatment regime.

## INTERACTION WITH THE PATIENT

The aim of this programme is to help patients to follow their treatment regime and enhance their sense of control over their condition. Although this will involve providing patients with information about heart failure and its treatment, the approach is not intended to be one in which patients are simply given advice or education about what they should do. Advice alone is not usually enough to change behaviour, for example, all patients will have been told how to take their medication but many will still be non-adherent. In this programme, patients will be encouraged to be actively involved in making decisions about how best to follow their recommended treatment.

Here are a few general points to help in the consultation about behaviour change:

- Patients will only remember small amounts of information.
  - Keep information to the minimum amount necessary for the patient to carry out a particular behaviour.
  - It is important that the points you want the patient to remember are made clearly and succinctly.
  - At the end of the session, summarise the main points you want the patient to remember.
- Make the patient a partner, indicating that you will work together to overcome any difficulties – the interaction with the patient is a

collaborative one, working towards behaviour change together. This differs from imparting advice that the patient is expected to follow.

- Adopt an open, questioning approach, even when dealing with sections that may be seen as purely educational. This will:
  - Help patients to see you as a partner rather than a teacher. The more involved they are in the process, the more likely they are to remember what is discussed and adopt what is agreed. This will also help to enhance self-efficacy (see below).
  - Help to reveal patients' illness beliefs and uncover any misconceptions or unhelpful beliefs they hold
- Encourage self-efficacy (confidence in ability to adopt specific behaviour).
  - Provide positive feedback about successful performance.
  - When using the problem-solving approach, help patients to adopt goals and strategies that they are confident they can follow.
  - If patient adopts a passive approach and asks to be told what to do, you can make suggestions about possible courses of action (e.g. 'some patients find it helpful to ....' but the patient must decide which strategy to adopt
- Observe patient responses and take your cues from them. Patients will vary widely, from those who are compliant, to those who are argumentative or those who express verbal agreement but then do not actually carry out the behaviour. The extent to which you need to

challenge them about their beliefs or behaviours will therefore vary.

When challenging beliefs/behaviours,

- taking a directive/persuasive approach (telling the patients what they *should* do) can lead to resistance from some patients e.g. 'yes, but....', or quiet resistance 'mmm' (also pay attention to person's non-verbal communication).
  - if a patient expresses disagreement, avoid arguing back! Instead open up the disagreement for discussion, suggest alternative formulations
  - explore why patient holds the belief
  - explore pros and cons of adopting/not adopting a particular behaviour
- Avoid falling back onto a lecturing approach

e.g. if you are met with silence from the patient

- Dealing with distress
  - this intervention is not designed to address clinical depression or anxiety so if you become concerned that the patient has become clinically anxious or depressed you should refer them for further input as per normal practice
  - however, in other patients, distress can still often arise from difficulties in coping with heart failure. Enabling patients to achieve



greater control over their condition and treatment will help to alleviate distress

- acknowledge and empathise with the emotion
- explore why the patient feels this way
  - how long have they felt like this?
  - what do you think is causing it?
- use the problem-solving approach to break down the problem (reason for distress) and generate possible solutions

## PROBLEM SOLVING

A problem-solving approach will be used to help patients overcome difficulties that act as barriers to adopting the behaviours required by their treatment regime. This does not mean solving the patients' problems for them, telling them what to do, but involves getting patients to think through their difficulties and decide on a solution. The approach used here is derived from the work of D'Zurilla & Goldfried (1971). The main components are:

- Problem Orientation

The way a problem is perceived by the individual is crucial for successful problem solving:

- Problems should be seen as soluble or controllable
- Problems need to be seen as 'difficulties to be overcome' rather than 'threats to be avoided'
- Individuals need to have confidence in their ability to overcome problems
- Problems attributed to personality or bad habit can be difficult to overcome and such beliefs need to be challenged
- Individuals need to be willing to devote the time and effort necessary to adopt the necessary behaviours.

Addressing problems using the following steps should help to increase patients' confidence in their ability to deal with the difficulties they

experience in following their regime. This in turn should aid the development of a more facilitative orientation to problem solving.

- Identify barriers (problems) to performing the behaviour as required
  - This involves identifying where a behaviour is not being performed as required and identifying what is acting as a barrier to performance
  - Patients may have difficulty with one or several aspects of their regime or may simply be overwhelmed by its complexity
  - An individual may be unaware of a problem e.g. aspects of unintentional non-adherence such as taking the correct amount of medication but at the wrong time, but gentle probing may uncover problems
  - Aspects of the regime will be new to some of the patients so it will be necessary to help them anticipate where difficulties or obstacles could arise
- Break the problem down
  - Think of what smaller problems are contributing to the overall problem
  - It will be easier to overcome a large problem if it is broken down into smaller components so that each barrier can be dealt with in turn
  - Think of psychological and social as well as physical barriers to carrying out the behaviour

- Generate alternative strategies to deal with the problem
  - Take each component of a problem in turn and try to think of as many solutions as possible. Patients and their partners/carers should be encouraged to try to do this together. Encourage them to be as imaginative as possible as the more solutions that are suggested, the more good ideas are likely to be produced.
  - Weigh up the pros and cons of each strategy. Do not dismiss any possible solution out of hand until all have been considered.
  - You can introduce strategies that 'other people in their position' have found useful, but recommending that a patient tries a particular strategy may meet with resistance e.g. lead to the patient responding with reasons why it will not work
- Selecting a strategy
  - While the nurse can help the patient to address problems and suggest possible solutions that the patient has not thought of, the decision about which solution will be adopted must be taken by the patient
  - Ensure that the strategy is within the patient's capabilities. Is outside help available if required? E.g. Social Services.
  - Patients should feel confident in their ability to carry out the strategy
- Employ the strategy and evaluate the outcome

- Patients should be encouraged to put the strategy into use from the time they are discharged from hospital (or before discharge, if appropriate)
- Problems may not be solved at the first attempt therefore it is necessary to review progress and amend the strategy where necessary
- An evaluation should be made of which aspects of the strategy were successful and what problems arose

Although these steps have been presented sequentially, successful problem solving is likely to involve movement back and forth between the different stages before the process is complete.

## CHALLENGING BELIEFS

The beliefs that individuals have about their illness and treatment will affect the likelihood of them following the recommended regime. The aim of the programme is to challenge unhelpful beliefs and promote more positive beliefs that will enhance self-management.

Unhelpful beliefs include:

- Catastrophising thoughts – e.g. If I go out I will overdo it and end up back in hospital
- Overgeneralisation – e.g. Taking diuretics means I can never go out
- All or nothing beliefs – e.g. If I don't exercise every day, I might as well not bother
- Attributing difficulties to personality – e.g. I have no willpower, I'm not a person who takes medication
- Placing too much responsibility on themselves for something that is not their fault – e.g. because I had to keep stopping for a rest, I ruined the day out for everyone else
- Jumping to conclusions based on insufficient evidence – e.g. whatever I do will make no difference
- Selective abstraction – concentrating on weaknesses and forgetting strengths, e.g. focussing on the aspects of their regime they have difficulty with and seeing this as evidence of uselessness, ignoring the aspects of their regime that they successfully follow.

Here are some ways of challenging unhelpful beliefs:

- Look for evidence which contradicts belief, e.g.
  - Probe for counter examples which contradict the unhelpful belief
  - Does this apply to every situation? Have there been times when it wasn't like this? E.g. when patient did successfully take their medication/follow diet etc
  - What was different about the times it didn't apply?
  - Highlight to patient how evidence contradicts their belief showing inconsistency in the belief
- Ask about possible alternative views
  - Are there any other ways of looking at this?
  - Do other people have different views?
- Look for advantages and disadvantages of this way of thinking
  - What is helpful about looking at situation in this way?
  - Is this way of thinking really helping? If not, what kinds of thoughts would help?
  - What might happen if.....
- Look for ways to generate more helpful thoughts
  - E.g. 'I can't do anything'. A more helpful thought might be 'I may not be able to do everything I used to but there are still things I can do.....' It is important that any failure is seen as having been specific to a particular aspect of a behaviour and is not over generalised to 'I can't do anything'.
  - E.g. 'I'll never be able to do it, it's too difficult'. A more helpful thought might be 'I've never done this before but that doesn't mean I can't

learn it. I could start by....' Challenge belief e.g. by focussing on areas where patient has been successful.

- E.g. 'I did that badly, I might as well not bother'. A more helpful thought might be 'I didn't do that as well as I could have but I can learn from that and do better next time'.



## STRUCTURE OF THE PROGRAMME

The programme will be led by a cardiac nurse specialist who will see patients with their partner or main carer where possible/applicable. The first and second sessions will take place before discharge from hospital and the third session will take place in the home within a week of discharge. The nurse will then contact the patient by telephone a week later. Patients will be able to contact the nurse by telephone if they have any concerns. During all of these contacts, the nurse will encourage patients to take a problem solving approach to managing their own condition.

## **SESSION ONE**

### **Objectives**

By the end of session 1, each participant should

- Be aware of the aims and structure of the programme
- Understand the link between heart failure and breathlessness, swelling, fluid intake and medication
- Understand the purpose of each of their medications

## 1.1 INTRODUCTION

**Aim** To introduce the programme

- Explain the purpose of the programme and what it will involve

### EXAMPLE

- While you have been in hospital, we have been giving you your medication every day and monitoring how you are. Now that you are going home, we want to make sure that you can continue to do these things so that you remain well. It is our aim to help you to learn some ways to make it easier for you to manage your heart failure when you get home.
- I'll see you briefly today, then I'd like to see you again, (with your partner) tomorrow. Also, I will come and visit you at home during the next week to see how you are getting on. You will also be able to contact me by telephone if necessary.

**Question** Do you have any questions about the programme?

## 1.2

**Aim** *To find out and clarify patients' understanding of heart failure*

- Use diagram of heart/lungs/body link to patient to help with understanding of link between heart/swelling/fluid/medication.
- Clarify any misconceptions
- Should any unhelpful beliefs arise, take the opportunity to challenge them

**Question** First of all, I'd like to ask you what you understand about what is happening in your heart.

*[It is important to start this way to help elicit the patients' understanding and beliefs about their heart failure]*

**Information** Provide an explanation of the role of heart failure in fluid balance, explaining how this gives rise to the symptoms and signs they have experienced.

### 1.3

**Aim** To ascertain and clarify patients' understanding of their medication

- Explain that each of the medications has a different purpose but they all help to make the work of the heart easier.
- Go through each medication and what its function is, clarifying any misconceptions
- Record each medication and its function on diagram

**Question** What medication are you taking?

(How often?)

(How much?)

(What does it do?)

#### **Information**

- Water tablets
- ACE inhibitors
- Betablockers
- Other medication

## SESSION CLOSE

- Inform patient that at next session you will be looking again at their medication and other aspects of their treatment and ways of helping to make it easier for them to manage their treatment. Ask them to arrange for partner/spouse to be present if appropriate/possible.

## SESSION TWO

- Session takes place before discharge from hospital
- Session will be attended by patient and spouse/partner/carer where appropriate/possible.
- This session will set out the treatment regime and look at ways to help make it easier for patients to follow.
- Although addressing barriers to behaviours will be covered mainly during Session Three, and is outlined in that section of the manual, if barriers to following the regime arise during the current session, they should be addressed when they arise.

### Objectives

By the end of session 2, participants should:

- Understand how to use the medication chart
- Understand how and when to weigh themselves and complete the weight chart
- Understand how and when to check for signs of swelling
- Understand the triggers for contacting you

- Understand the need to manage their fluid intake and have identified ways of reducing it if necessary
- Understand the need for a low salt diet and have identified ways of reducing their salt intake where necessary
- Understand the importance of keeping active and have identified ways of incorporating regular physical activity into their daily lives
- Have identified possible ways of dealing with any foreseen problems in following their treatment regime



## 2.1

**Aims** To introduce treatment regime.

- Give an overview of the programme

### EXAMPLE

- In managing your heart condition there are several things that you need to do, like take medication, make some dietary changes, monitor yourself for signs of fluid retention and incorporate some exercise into your daily routine.
- We know that it can be difficult to follow some parts of this routine and our aim is to help you to learn some ways to make it easier for you
- We will cover some of these things today and then I will visit you at home in the week after you are discharged to see how you are getting on
- You will also be able to telephone me (during office hours) if you have any problems

**Question** Any questions?

## 2.2

**Aim** To introduce medication chart and find most suitable ways of incorporating medication into daily regime

**Question** The last time we met, we spoke a little about the medications you are taking. Do you have any questions about what we talked about at the last session?

- Explain that you want to look at ways that could help to make it easier for them to remember to take all their medication as prescribed. One way is to use a medication chart which they complete every day.
- Introduce and explain monthly tick chart and again go through which medications they take, when and how much.
- Suggest that the chart will make it easier for them to always remember their medication.
- Explain that it will be easier for them to remember their medication if it becomes part of their daily routine, like brushing their teeth.
- Ask participants to think through the most suitable time to take their tablets by thinking through a typical day..... Let's start with your water tablet, which probably causes most disruption to people's routines
- Use problem-solving approach to ask patient and partner to generate possible solutions to the most suitable time(s) to take diuretics.
- Use same approach for any other medications that have to be taken at different times.

## **Probes**

Where would be the most useful place to keep the medication chart so that it acts as a reminder? (In same place as medications)

What other triggers can they use to help them remember?

Can they foresee any problems in taking their medications every day as prescribed?

Can they think of particular times/situations that may prove more difficult?

## 2.3

**Aim** To ensure patient understands and can follow weight monitoring regime

- Ensure that patient will have weighing scales by time of discharge
- Explain the purpose of weight monitoring
- Explain how and when to weigh and complete the chart
- Explain what to do in the event of weight change
- Identify barriers to weight monitoring and problem solve with patient

### Information

- If the heart is not working as well as it should, you may start to retain fluid. It is possible to detect this quickly by monitoring your weight on a daily basis to watch out for any unexplained weight gain.
- Weigh yourself at the same time every morning, after going to the toilet but before breakfast and before getting dressed
- Use the same scales every day
- Fill in your daily weight chart
- If you gain (or lose) 1-2 lbs (1 kilo) one day and the same again the next day, OR if you notice a more gradual change in your weight of 3-4 lbs (2

kilos) over 1 – 2 weeks, contact me - it may be necessary to alter your water tablet prescription and look at what other factors might be causing the weight change

### **Probes**

Can you foresee any problems in monitoring your weight?

What would be the best place to keep the scales and chart to help you remember?

## 2.4

**Aim** To ensure patient understands and can follow monitoring for oedema

- Explain the purpose of checking for swelling
- Explain how and when to check ankles and ask patient to practice
- Explain what to do in the event of increased swelling
- Identify barriers to checking for swelling and problem solve with patient

## Information

- Another early sign of fluid retention is swelling around the ankles or stomach
- To check for this, look to see if the skin around your ankles/feet appears stretched and shiny
- When you press on the skin around your ankles, does the indentation remain?
- Have you noticed that your clothing/belt is getting tight or your shoes do not fit?

- Check every evening for any of these signs of swelling. If you notice signs of increased swelling over 3 consecutive days, contact me as we may need to adjust your water tablet prescription and look at what might be causing the fluid retention

### **Probes**

Can you foresee any problems in checking your ankles?

## 2.5

**Aim** To ensure patient understands and can follow fluid monitoring regime

- Explain the purpose of monitoring fluid intake
- Find out how much the patient drinks in a typical day
- Identify ways of reducing fluid intake where necessary

### Information

- It is important to take in enough fluid for the body's needs but too much can cause fluid retention
- Remember that all fluids are included e.g. water, tea, alcohol, soup
- You are advised to take in about 1.5 – 2 litres (2.5 – 3 pints) a day. This amounts to about 10 average sized teacups.
- It will help if you pace the amount you drink throughout the day. Discuss times when they like to drink and assess whether it is within the limit.



## Probe

- Take me through a typical day, telling me about what you drink during the day. Ask specifically about water, tea, coffee, milk with cereal, juices, alcohol, night time drink.
- Can you think of ways to reduce the amount of fluid. These need to be specific, e.g.
  - Change from mug to cup
  - Cut out cup at specific selected time(s) of daynot just a more general 'try to cut down a bit on tea'.
- Can you think of ways of quenching thirst without drinking too much. E.g. suck ice cube, drink cold fluids rather than hot, rinse mouth out regularly with cold water, avoid salty/sugary foods.

## 2.6

**Aim** To ensure patient understands and can follow low salt diet

- Explain the purpose of reducing salt intake
- Find out if patient is taking too much salt
- Identify ways of reducing salt intake where necessary

### Information

Salt can make you

- retain more fluid
- more thirsty, making it more difficult to stick to the recommended daily fluid intake
- it is therefore important to eat a diet which is low in salt

### Probe

- Can you think of ways that you can reduce the salt in your diet?
  - Do not add salt to your food while cooking

- Do not add salt to your food on the plate
  - Use herbs and spices as an alternative to salt
  - Avoid ready meals, tinned foods, smoked meat and fish, cheese, bacon and ham, salted snacks such as crisps and nuts and sausages or other made up meat dishes such as beef burgers and pies.
- 
- Can you think of times or situations when it may be more difficult to stick to a low salt diet?

## 2.7

**Aim** To ensure patient is aware of importance of keeping active and to discuss what activities they can do.

- Explain that we know that many people with heart failure will have concerns about taking exercise but it is important for them to keep as active as possible.
- Check patient's understanding of what is meant by exercise – that it does not just mean sports but that many activities such as walking, stair climbing, gardening, dancing can be included.
- It may be helpful to ask patient to think of benefits of keeping active
  - Strengthen heart muscle
  - Improve circulation
  - Make you feel better
  - Help to lose any excess weight
  - Can help with other health conditions
- Explore type of exercise that would be most suitable for patient (usually walking).
- Explore ways patient will incorporate activity into daily routine.
- Include ways of ensuring they won't 'overdo it':
  - Exercise with a friend, partner
  - Build up slowly
  - Exercise as much as you can without getting tired, out of breath or making your heart beat too fast
  - Stop if feeling dizzy and rest for a few minutes
  - If walking, find a route which is reasonably flat

Use problem-solving approach to address any barriers to exercise

## SESSION CLOSE

- Give patient a copy of the heart failure booklet and supply of charts
- Explain that the booklet will act as a reminder of the things that they can do to keep feeling well. The charts will help with their medication and monitoring of weight and swelling.
- Tell patients that you will see them and their partner/main carer at their home within the next week. Arrange suitable time.
- Remind them that they can contact you if they have any problems in the meantime

## Questions

Do you want to ask me anything about what we have covered today?

## **SESSION 3 – HOME VISIT**

### **Objectives**

By the end of session 3, patients should have

- Reviewed how they are getting on in each of the areas covered in the intervention
- Identified aspects which they found more difficult
- Identified possible solutions to these problems, revising and adapting where necessary

### 3.1

**Aim** To assess how successful patients have been in following their regime, and to address any barriers to following the regime using the problem-solving approach.

General points for dealing with setbacks:

- Patients with heart failure have to follow a complex regime and will not always be successful in following all aspects of their regime.
- Challenge any beliefs patients have about setbacks resulting from personal inadequacy
- Positive efforts to overcome barriers should be reinforced regardless of outcome

General points to review if patients have been able to perform required behaviours and to address any barriers (problems):

- Take each behaviour in turn – adherence to medication, self-monitoring etc. Each of these is covered in more detail below.
- Ask patients to feedback on how they are getting on with each behaviour
- Emphasise that you would like them to tell you any difficulties they have had in adopting the behaviour as well as positive experiences.
- Give positive reinforcement for effort in tackling behaviour even if not completely successful
- Address each problem in turn using the problem-solving approach as described in Session 1.



## 3.2

**Aim** To address any barriers to taking medication

- Ask patients for feedback on how they managed with their medications and the tick chart
- Patients may be very reluctant to admit to non-adherence, wanting to appear to be 'good' patients. Acknowledge that it can be very difficult to follow recommendations all the time and you want to look at ways that you can work together to overcome any difficulties the patient has.

### **Probe**

- When people have to take several tablets, it can be difficult to always remember to take them every day, exactly as prescribed. Do you find that this has sometimes been a problem?

Use the problem-solving approach to break down how the problem arises, e.g.

- Are they more likely to forget in certain situations?
- Do they remember to take their tablets every day but have problems taking them at the right times e.g. before/after meals?

- What do they do if they forget and what *should* they do e.g. double up next dose/ reduce time between next doses until they 'catch up'/ skip forgotten dose

## Probe

- One of the reasons that people stop taking their medications is that they feel they are getting some unwanted effects of the medicines. Have you experienced any side effects from your medications?
  - Advise any ways there are to avoid these side effects
  - When people experience side effects they can sometimes be tempted not to take their tablets as prescribed. If you do experience any side effects, always discuss them with your doctor (or you can telephone me) rather than not taking them. It may be possible to change to another similar medication which will suit you better

## Probe

- Are there any other difficulties with following medication regime? E.g.
  - Patients may express a general reluctance to take several medications
    - e.g. not wanting to see themselves as a 'tablet person'
    - e.g. believing that they should give their body 'a rest' from medication

Explore these beliefs further and challenge unhelpful beliefs using the techniques described above.

### 3.3

**Aim** To address any barriers to daily weighing

- Check weight chart
- Ask patients for feedback on how they managed with daily weighing
- Address barriers to daily weighing using problem solving techniques

#### **Probe**

Is there anything that has made it difficult for you to weigh yourself every day?

E.g....

- Forgetting to monitor
  - In what situations do they forget?
  - What would make it easier to remember?
  - Where could they put chart to remind them (if current place not working)?
    - e.g. put up chart in place where it will be seen first thing in the morning
    - e.g. put up sign in prominent place
  - What else might help them to remember?
    - e.g. partner can help by reminding
- Would rather not know
  - If patients feel that there is little they can do to change their heart condition they may feel that daily weighing is pointless. Unhelpful beliefs need to be challenged.
- Other barriers?

### 3.4

**Aim** To address any barriers to checking oedema

- Ask patients for feedback on how they managed with checking oedema
- Address barriers to daily monitoring for oedema using problem solving techniques

### Probe

Is there anything that has made it difficult for you to check your ankles every day? E.g.

- Forgetting
- Would rather not know
- Other barriers?

### 3.5

**Aim** To address any barriers to maintaining appropriate fluid intake

- Ask patients for feedback on how they managed with fluid intake
- Address barriers to keeping within recommended daily fluid intake
- Revisit the approach used in Session Two:
  - Take me through a typical day, telling me about what you have been drinking during the day. Ask specifically about water, tea, coffee, milk with cereal, juices, alcohol, night-time drink.
  - Work out ways to pace fluid intake during the day (bearing in mind what didn't work first time around).
  - Ask patients if they can remember ways of quenching thirst without drinking too much. E.g. suck ice cube, drink cold fluids rather than hot, rinse mouth out regularly with cold water, avoid salty/sugary foods – what will patient find most useful?

### Probe

Have there been any times/situations when it has been harder for you to keep to the recommended daily fluid intake?

### 3.6

**Aim** To address barriers to following a low salt diet

- Ask patients for feedback on how they managed with reducing salt in diet
- Address barriers to reducing salt intake

### Probes

What difficulties have you had in following a low salt diet? Examples:

- Food doesn't taste as good
- It's more convenient to use ready meals
- It's difficult to eat different foods from the rest of the family
- I snack on crisps when I'm bored or fed up
- I just haven't got any willpower

Use problem-solving approach to generate solutions to address these problems.

- Try allowing yourself a set period to try to get used to the taste of food with less salt
- Reduce salt intake gradually over a set period
- What healthier alternatives could be eaten as snacks?
- What alternatives are there to eating when bored?
- Negotiate with family ways of incorporating a low salt diet

Can you remember ways that you can reduce the salt in your diet?

- Do not add salt to your food while cooking
- Do not add salt to your food on the plate
- Use herbs and spices as an alternative to salt
- Avoid ready meals, tinned foods, smoked meat and fish, cheese, bacon and ham, salted snacks such as crisps and nuts and sausages or other made up meat dishes such as beef burgers and pies.

### 3.7

**Aim** To address barriers to exercise

- Ask patients for feedback on how they managed with exercise
- Explore patient's concerns about physical activity and help to problem solve ways of overcoming concerns about incorporating activity into their daily routine.  
E.g. Patients may be particularly concerned about health risks. Reiterate the benefits of exercise for heart failure and ways of ensuring they won't 'overdo it' i.e.
  - Exercise with a friend
  - Build up slowly
  - Exercise as much as you can without getting tired, out of breath or making your heart beat too fast
  - Stop if feeling dizzy and rest for a few minutes
  - If walking, find a route which is reasonably flat
- Explore other barriers to exercise which might include
  - I'm too old to exercise, what difference can it make now?
  - Exercise is boring
  - I don't have time
  - I can't afford it (e.g. to join a health club)
- Use problem solving approach to generate possible solutions to overcome these barriers e.g.
  - Challenge beliefs about exercise not being useful
  - Ask patient to think of other activities which they might find



more enjoyable

- Ask patient to think about ways of incorporating activity into their normal day so that it is not an additional 'chore'.
  - Increasing normal daily activities such as walking and stair climbing is free
- 
- Help patient to think of how they will plan to incorporate activity into their day e.g.
    - What they will do
    - For how long
    - At what time
    - Ensure that plan seems realistic

## SESSION CLOSE

- Advise patient and partner that you will contact them by telephone in about a week to see how they are getting on.
- Remind them that they can contact you if they have any problems in the meantime

## **TELEPHONE FOLLOW UP**

Problems are not always resolved at the first attempt and the problem-solving process involves continual review.

### **Objectives**

- To provide an on-going link between nurse and patient
- To evaluate the ongoing effectiveness of patients' problem-solving strategies and amend them where necessary
- To identify any new problems
- To provide encouragement and reinforcement
- To remind patients that they should telephone in response to any triggers.
- The aim of the telephone follow-up is to assess how successful patients have been in following their regime, to evaluate the effectiveness of their problem-solving strategies and to amend them where necessary.

## READMISSIONS TO HOSPITAL

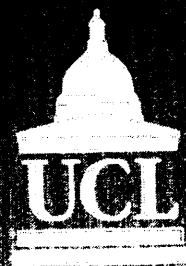
- Visit patient before they are discharged from hospital
- Explore factors that led to current admission
- If these were related to difficulties with self-management, problem-solve ways that this could be avoided in future
- Reinforce what has been covered in the intervention
- Remind patients to contact you if they show signs of deterioration

## DEALING WITH POSSIBLE SCENARIOS ARISING WITH PATIENTS DURING THIS INTERVENTION

- Patient attentive only to one doctor
  - Ask doctor to accompany you and tell patient that what you are going to tell them is very important.....
- Patient maintains that some people take tablets, some don't and he is one who doesn't
  - Ask why he defines himself this way
  - Ask if he has taken any tablets, which ones, ask how they are different, what would make him feel the same about the tablets he doesn't take as the ones he does?
  - Challenge his belief about his sense of himself as a person, it is untenable if he is taking some tablets
  - Resist reverting to stressing the importance of taking tablets
- Patient anxious about other aspects of care and keeps deviating from subjects in programme
  - Acknowledge patient's concern, promise to sort it out, show patient that you are writing it down and will come back to it. Bring patient back to intervention by saying you need their full attention
- Disruptive, unhelpful carer
  - Put responsibility back on them e.g. How will you help patient to.....
- Patient who had put on weight but not contacted nurse
  - Make it clear that you want them to call you, it's no bother....
- Patient reluctant to seek help, I'm not the kind of person who looks for help
  - Challenge patient on this – they came for help by coming to hospital

- So you're the kind of patient who delays looking for help
- Do you delay everything e.g. taking car to garage if petrol tank was leaking? Show patient how bizarre this belief is
- Patient who agrees with everything but it is not clear if they are taking it in
  - Adopt questioning approach – see general guidelines for intervention
- Patient very enthusiastic but perhaps unrealistic
  - Look at targets they have set, break it down, set lower goal, review success at home visit
- Patient reluctant to weigh
  - Think of it like brushing your teeth – it only takes 30 seconds

## **APPENDIX B. INTERVENTION BOOKLET AND CHARTS**



## Managing Heart Failure



This booklet has been written to explain the many things you can do to help you manage your heart failure and so keep you feeling as well as possible.





## Your Cardiac Nurse

Name: \_\_\_\_\_

You can contact your cardiac nurse

Monday - Friday

09.00 - 16.30



Direct Line/Voicemail

Or

Bleep

If you are unable to contact your cardiac nurse directly please leave a message on voicemail and your call will be returned as soon as possible. If you do not have a phone in your home, establish before leaving hospital the best times to contact your nurse.

## HEART FAILURE

The term heart failure may sound alarming but simply means that the muscular pump of the heart is not working as well as it should. This may cause breathlessness and tiredness. It can also cause a build up of fluid in the body, especially in the ankles or lungs.

Heart failure is a very common condition and in recent years there have been enormous advances in our understanding of heart failure and its treatment.

## HOW YOU CAN HELP YOURSELF

There are several things that you can do to help you remain well. These are covered in more detail in the following pages and include:

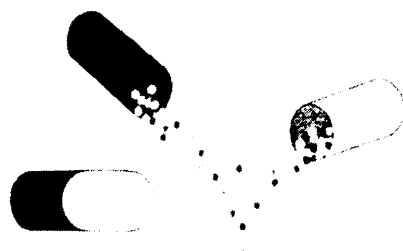
- Taking your medication as prescribed
- Monitoring your symptoms for signs of change
- Being careful about the amount you drink
- Making a few simple lifestyle changes

## MEDICATION

There are a number of medicines available for heart failure. Your doctor will decide on the most suitable treatment for you and may give you one or more of these different types of medicines.

Some medicines are designed to help your symptoms and will make you feel better. With others you may not notice any difference but they have been shown to improve the strength of the heart muscle over a period of time.

Your doctor may gradually introduce new medicines or change your medicines after careful assessment.



**To get the most from your medication:**

- Take your medication every day as prescribed by your doctor. Complete the medication chart to help you remember
- Do not stop taking any medicines without talking to your doctor/nurse
- Make sure you keep an adequate supply of your medicines
- Keep an up to date list of all your medicines and carry it with you
- Bring your medication list with you every time you see your doctor/nurse/pharmacist



## MONITORING SYMPTOMS

As a patient with heart failure you can have long periods of feeling well and other times when your symptoms may return. By learning to recognise signs of change you can get help at an earlier stage. Small changes in your treatment at this stage usually prevent more serious problems developing and will keep you feeling well.

One of the symptoms of heart failure is the tendency to retain fluid. You can check for early signs of fluid retention by:

- weighing yourself every day
- checking for signs of swelling in your ankles
- noticing if you become more breathless



## Daily Weighing

One of the ways of checking for early signs of fluid retention is to weigh yourself every day. If you gain weight over a number of days, this might be a sign that you are building up too much fluid.

To check if this is happening:

- Weigh yourself every morning, after going to the toilet but before breakfast and before dressing
- Use the same scales and weigh yourself in the same way every day
- Complete your weight chart
- If you find you are consistently gaining or losing weight, you should contact your cardiac nurse. Everyone's weight varies a little from day to day but if you gain or lose 2lbs (1kilo) on 2 consecutive days, *or* 3-4 lbs. or more over a period of 1-2 weeks, contact your cardiac nurse



## Swelling

Another sign that you may be retaining too much fluid is if your ankles are more swollen than usual.

You may notice that:

- the skin around your ankles/feet looks more stretched and shiny than usual
- when you press on the skin around your ankles, the indentation remains
- your shoes feel tight

Check for signs of swelling at the same time every morning, and make a note on your chart.



If you notice signs of increased swelling for 3 consecutive days, contact your cardiac nurse.





## Breathlessness

Increased breathlessness may be a sign that fluid is starting to build up in your lungs. If you become more short of breath when doing your usual activities or if you find you are waking at night due to breathlessness, contact your cardiac nurse.



## FLUID INTAKE

Patients with heart failure need to take a little extra care with the amount of fluid they drink. You need to drink enough to allow your kidneys to work properly but not so much that you retain excess fluid.

To help you do this:



- Drink 1½-2 litres (or 2½-3½ pints) of fluid a day only. (This is about 10 average size teacups.) Include all types of fluid in this total e.g. water, tea, coffee, juices, alcohol, soup etc.
- Plan how you will pace your fluid intake over the course of the day

- On hot days, or if you are physically active and perspiring a lot, then you can drink 1-2 extra cups of fluid. You may find it useful to rinse your mouth out with cold water or suck ice occasionally if you have reached your fluid limit
- Avoiding salty and sugary foods will help to prevent you getting too thirsty



Diuretics (water tablets) are designed to prevent you retaining too much fluid by making you pass more water. You will soon learn how often you usually pass water.

## LIFESTYLE ISSUES

Some other changes can also help you to control your symptoms and improve your quality of life.

### Keeping active

- Keeping active will improve your circulation, strengthen your heart muscle and make you feel and sleep better
- Try to make sure that you do some physical activity every day. Your nurse will discuss activities that most suit you

Activities can include walking regularly, gardening, bowling, swimming, golfing or any other physical activity you enjoy.





- Build up your activity gradually, doing a little more each day. Try to avoid sudden strenuous exertion
- Rest is also beneficial so remember to include a quiet period every day - some people find a short nap helpful. If you have been very active on one day, it is natural for you to feel more tired and need a little more rest the next day
- If you are physically restricted for other reasons, you can keep active by doing some exercises in your chair or bed. Your cardiac nurse will discuss these with you



## Salt Reduction

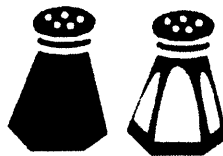
Salt can make you retain more fluid and feel more thirsty, making it harder to follow recommendations about daily fluid intake.

Reducing the amount of salt in your diet can help to ensure that you do not retain too much fluid.

To reduce your salt intake:

- Avoid foods with a high salt content. These include: salted crisps and nuts, smoked meats and fish, bacon, ham and sausages. Remember that all processed foods have some added salt
- Do not add salt to your food when cooking or at the table
- Add herbs and spices as an alternative to salt

Avoid salt that is termed 'low salt' as it contains other minerals that can be harmful in large doses to people with heart failure



## Smoking



- If you smoke, stopping now is very important for your health
- If you continue to smoke you may make your condition worse
- For help in giving up smoking contact the NHS Quitline

## Weight reduction

- If you are overweight, your heart has to work harder. It is important to lose weight slowly and steadily. Aim for a weight loss of no more than 2lbs. (1 kilo) per week.
- Any sudden unexpected weight loss should be discussed with your cardiac nurse (see section about daily weighing)



## Alcohol

- You are advised to drink no more than 1 - 2 units of alcohol a day. This should not be saved up for one or two evenings! One unit is equal to  $\frac{1}{2}$  pint of normal strength lager or one pub measure of spirits or one small glass of wine
- REMEMBER that alcohol forms part of your daily fluid intake

If you have been told that alcohol has caused your heart failure, then you should avoid alcohol completely.





## Immunisation

People with heart failure are more prone to chest infections. Ask your GP to arrange the following vaccinations:

- Yearly flu jab to help prevent you developing extreme bouts of colds and flu
- Pneumonia vaccination (if you have not had one in the last 10 years)

Try to avoid unnecessary contact with people who are unwell with chest infections.



## SUMMARY

There are many things you can do to keep you feeling as well as possible. The purpose of this booklet is to act as a reminder of what you can do and when you may need to contact your nurse.

Every day, remember to:

- Take your medication
- Weigh yourself
- Check for signs of swelling
- Complete the charts that are included with your folder

If this booklet has raised any further questions for you, your cardiac nurse will be happy to discuss them with you.

## Weight Chart

MONTH \_\_\_\_\_

Date	Weight	Swelling	
		Yes	No
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

Date	Weight	Swelling	
		Yes	No
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

- Weigh yourself every morning, after going to the toilet but before breakfast and before dressing
- Use the same scales every day
- If you gain or lose 1-2lbs (or 1kilo) on 2 consecutive days, or 3-4lbs or more over a period of 1-2 weeks, contact your cardiac nurse on
- Check your ankles every morning. If you notice signs of increased swelling for 3 consecutive days, contact your cardiac nurse

# MEDICATION CHART

MONTH \_\_\_\_\_

Medication		Purpose	Amount	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Morning																																		
Afternoon																																		
Evening																																		
Night																																		

## **APPENDIX C. HOSPITAL GUIDELINES FOR MANAGEMENT OF HEART FAILURE**

## Guidelines for the Management of Heart Failure

*The aims of these guidelines are to:*

- 1. Establish or refute the diagnosis of heart failure.**
- 2. Optimise the therapy for patients with heart failure.**
- 3. Stabilise patients prior to discharge from hospital**

Definition of heart failure

### **Essential features**

- Symptoms of heart failure (breathlessness, fatigue, ankle oedema)
- Objective evidence of left ventricular systolic dysfunction (usually echocardiogramme)

### **Non-essential features**

- Response to treatment directed towards heart failure

Patients with suspected heart failure will be admitted by the take team. These patients should then be referred to the cardiology team via the cardiology SpRs (bleep 3038/3096) or Patsy Hargrave (Specialist heart failure nurse) during normal working hours. Thereafter the patients will receive shared care (according to this guideline) with regular advice by a cardiology SpR and/or consultant. **Patients will remain primarily under the care of the admitting team with advice from cardiologists.**

On admission obtain a full history and record symptoms of heart failure. Record clinical signs of heart failure.

Arrange the following investigations if not already done U&Es, ABGs, TFT, FBC, ECG, CXR, echocardiogram.

When a diagnosis of heart failure has been confirmed, then potential causes should be investigated.

Causes of heart failure to consider include; ischaemic heart disease, hypertension, valvular heart disease, thyrotoxicosis, toxins e.g. alcohol, viral myocarditis, haemochromatosis and infiltrative disease, persistent tachycardias, atrial fibrillation or one of the cardiomyopathies.

Additional investigations to consider include ferritin, viral screen (coxsackie, enterovirus), auto-anti-bodies.

### NYHA association classification of heart failure

- Class I Asymptomatic. No limitation of ordinary physical activity
- Class II Mild. Slight limitation of physical activity
- Class III Moderate. Limitation of normal physical activity such as walking on the flat causes symptoms
- Class IV Severe. Symptoms of heart failure present at rest and increase with any physical activity

### **Treatment 1   *Acute Severe Pulmonary Oedema***

1. high flow oxygen by mask
2. intravenous loop diuretic e.g. frusemide 40-80 mg
3. intravenous opiate e.g. diamorphine 2.5-10mg with anti-emetic
4. identify and treat any precipitating or exacerbating factor e.g. atrial fibrillation, chest infection, unstable angina

Additional measures that may be of use:

1. intravenous aminophylline infusion
2. venesection
3. intravenous nitrate infusion
4. consider non-invasive ventilation
5. inotropes

### ***Treatment 2*   **More stable patients****

Review current medication and omit any potential aggravating agents (NSAID's, steroids, Ca antagonists).

**Diuretics** are indicated in patients with symptomatic systolic dysfunction and usually provide rapid relief of symptoms.

- In patients who are not receiving any diuretic it is reasonable to start at a low dose e.g. 40mg of frusemide orally and assess clinical response.
- In patients who are already receiving oral frusemide at doses of 40-80 mg conversion to intravenous frusemide may improve diuresis.
- Patients with mainly right-sided failure will need IV diuretics for several days. GI tract oedema can often reduce absorption of oral medication. During this period aim for 1kg weight loss daily, with close monitoring of U&Es and creatinine.
- Avoid over-diuresing the patient prior to initiation of ACE inhibitor therapy as dehydration increases the potential for renal side effects.
- Treatment with diuretics should be directed towards control of symptoms and aim for optimal dry weight.
- Potassium levels should be kept towards the high side (aim for 4.0 to 5.5 mmol/l)

In patients who do not respond to initial diuretic treatment, the following changes in medication may be of use:

- Increasing I.V. frusemide dose or increasing to twice daily dosing
- Combination of loop and bendrofluazide 2.5 mg od. Monitor renal biochemistry and electrolytes on alternate days.
- Combination of loop and metolazone 2.5 mg od or alt days. Monitor renal biochemistry and electrolytes daily.

## ***Drugs of prognostic benefit in heart failure***

### **ACE Inhibitors**

ACE inhibitors improve the prognosis in heart failure at all stages of the disease. Once LV dysfunction has been confirmed introduce **ACE inhibitor** unless contraindicated. Therapy should be initiated at low dose and increased to therapeutic doses if tolerated.

N.B. ACE inhibitors and potassium retaining diuretics **can** be give together, but the plasma potassium levels will need checking.

*Recommended doses of ACE inhibitors which have been approved by C&I HA for use in heart failure in the community (on the basis of evidence and cost)*

<b>Drug</b>	<b>Starting Dose (mg)</b>	<b>Target Dose (mg)</b>
Captopril	6.25 tds	25-50 tds
Enalapril	2.5 bd	20 bd
Lisinopril	2.5 od	20 od
Ramipril	1.25 od	5 bd

### ***Spironolactone***

If symptoms persist or class III/IV heart failure and on optimal dose of ACE-inhibitor consider initiation of spironolactone 25 mg od.

In patients with hypokalaemia, spironolactone may be especially useful to maintain serum potassium levels, but 25mg bd or more may be needed.

### ***Beta-Blockers***

Beta blockers are of prognostic benefit in patients with heart failure. They should not be introduced in patients until a stable (see below) period of three months has elapsed.

In patients where ischaemia or uncontrolled atrial fibrillation contributes to worsening heart failure beta-blockers may be considered, and the cardiology team will direct their use.

N.B patients who are admitted with worsening heart failure who are established on beta-blockers as part of their heart failure treatment, should not have their beta-blockers stopped. It is better to reduce the dose of beta-blocker and increase diuretic dose. **THIS DOES NOT APPLY TO PATIENTS ADMITTED IN SEVERE PULMONARY OEDEMA, IN WHOM BETA-BLOCKERS SHOULD BE WITHELD**

### **Additional Medication**

#### **Digoxin**

Digoxin seems to provide symptomatic benefit in patients with chronic heart failure – even in sinus rhythm. You may want to consider adding digoxin to patients in whom symptom control is difficult.

N.B. do not add digoxin unless potassium is  $\geq 4.0\text{mmol/l}$



### **Stabilisation of patient**

A stable patient will have

- Well controlled symptoms
- Stable body weight
- Stable electrolytes and creatinine

At this stage patient will be randomised to nurse led care or not. Please do not discharge during this period or later medication.

Patients should be given an information sheet (available on wards), with advice tailored to their needs included.

Follow-up after discharge should be arranged for 6 – 8 weeks with a consultant cardiologist, please liaise with one of the cardiology SpR prior to making the appointment. Other medical follow-up can be arranged as appropriate.

These guidelines are complimentary to the district wide heart failure guidelines which will be available through casualty and which you may wish to read. It is our intention to ensure a consistent approach to heart failure irrespective of which health care system or professional a patient encounters.

## **APPENDIX D. HOSPITAL HEART FAILURE LEAFLET**

(This appendix reproduces the text contained in the leaflet, rather than being a copy of the leaflet itself)

## Heart Failure

**This information leaflet is for patients who have heart failure. It explains what it is, what symptoms to expect and the treatment available.**

### **What is heart failure?**

This sounds alarming but just means that your heart's pumping power is weaker than normal, so that it is failing to pump enough blood around your body to supply all its needs.

For most patients **heart failure is a chronic condition**, which means that it is a long-term problem and can be treated but not cured.

### **What are the usual causes of heart failure?**

- A previous heart attack
  - High blood pressure
  - Heart valve disease
  - Long term excess alcohol
- What ever the cause may be, the treatment will mostly be the same.

### **What are the signs and symptoms?**

#### **The most common symptoms are:**

- Tiredness and weakness; you may find that walking, going upstairs or carrying groceries can be difficult.
- Shortness of breath when doing exercise or when lying down at night;
- Swelling of ankles and legs.

**Please note** - some other medical problems can cause the same sort of symptoms.

### **What is the treatment?**

Treatment is usually very effective and is aimed at:

- getting you back to as normal a life as possible;
- reducing your symptoms;
- preventing your heart failure from getting worse.

#### **Your treatment may include:**

- **Medicines** - prescribed by your doctor
- **Changing your life style** by exercise, diet, and not smoking - you can take an active part in this
- **Surgery** – very occasionally the cause of heart failure can be put right by surgery, such as by having a heart valve replaced

### **Medicines**

The medicines usually prescribed by the doctor to treat heart failure include **diuretics** and **ACE inhibitors** - which may be started first, with **beta blockers** being added later. Sometimes **digoxin** is also given, depending on your symptoms. Your specialist doctor will select a combination of these, and sometimes, other drugs to suit your needs. **For the side effects of these medicines please check the information included with your prescription.** If you want to discuss the side effects further, do ask your doctor or pharmacist.

### 1) Diuretics

Diuretics (water pills) help to remove excess fluid and salt from the body, (making you pass more urine). By helping you get rid of excess amounts of fluid, diuretics help to reduce ankle swelling and improve breathing.

### 2) ACE inhibitors

These medicines relax the arteries (blood vessels) making it easier for the heart to pump the blood around the body. They make you feel better and improve your life quality.

You will start on a low dose and then gradually increase the amount, depending on your blood pressure and kidney function.

### 3) Spironalactone

This drug has been shown to give added protection to some patients with heart failure. You may not feel any different but it can still have long-term benefits.

### 4) Beta-blockers

Beta-blockers slow the pulse rate and reduce the workload of the heart with useful long-term benefits. If you have **asthma** you must tell the doctor prescribing these tablets; it often means you will not be able to take these drugs.

### 5) Digoxin

Digoxin has been used to treat heart failure for many years and continues to be used for some patients. It is used to strengthen the heart beat and if the beat is irregular it can help steady this.

### Changing your lifestyle

You can help to prevent the heart failure getting worse by:

- **Reducing your weight** (if you are overweight) - by planned exercise and diet.
- **Changing your diet** – a low salt diet is usually advised; avoid adding salt to food, and buying food with high salt content.
- **Changing your fluid intake** – it is important to get the balance right, not too much and not too little. You should only drink 1½ – 2 litres (2½ - 3½ pints) a day, about 10 average size teacups. Fluids including water, tea, coffee, juices, alcohol and soup.
- **Not smoking** – advice is readily available via the “NHS Quitline” on 0800 002200
- **Keeping active and exercising regularly** – walking and swimming are good forms of exercise. Do as much exercise as you feel comfortable with every day and gradually increase the amount.
- Moderating your weekly intake of alcohol to a maximum of 1-2 units per day for women, and 2-3 units per day for men; (one unit = a small glass of wine/pub measure of spirits/½ pint of standard strength beer). You should have at least 2 alcohol free days per week.
- If you have been told your heart failure was caused by alcohol you should stop drinking alcohol completely.

### Surgical treatment

Most heart failure can be treated medically, as above, but a small number of patients may benefit from surgery.

Your doctor will discuss this option with you if it is necessary.

### You may want to discuss the following issues further with your doctor:

- **Infection** – people with heart failure are more at risk from chest infections. Ask your GP to arrange the following immunisations for you:
  - Yearly flu jab to help prevent extreme bouts of cold or flu.

- Pneumonia vaccination (if you have not had one in the last 10 years).
- **Work** - you may have some restrictions depending on your job
- **Exercise** - you may wish to discuss your individual needs.
- **Sex** - people with heart failure are often concerned about sexual activity, but you can resume a sexual relationship with your partner once you feel ready to do so. As with other forms of activity you may become tired or breathless. If this happens stop and rest for a short time. This may also prompt you to explore different approaches which can still be very enjoyable.
- **Driving** - it is usually all right to drive but you should discuss it with your doctor, as it will depend on the type of licence you hold. You should also tell your insurance company.
- **At night** – some people find sleeping with an extra pillow helpful.

**Any further questions?**

If you have any more questions please discuss them with your doctor.

## **APPENDIX E. STUDY QUESTIONNAIRES**

1. In general, would you say your health is:

(Circle One Number)

- |                 |   |
|-----------------|---|
| Excellent ..... | 1 |
| Very good ..... | 2 |
| Good .....      | 3 |
| Fair.....       | 4 |
| Poor.....       | 5 |

2. **Compared to one year ago**, how would you rate your health in general **now?**

(Circle One Number)

- |  |   |
|--|---|
| Much better now than one year ago .....    | 1 |
| Somewhat better now than one year ago..... | 2 |
| About the same as one year ago .....       | 3 |
| Somewhat worse now than one year ago ..... | 4 |
| Much worse now than one year ago.....      | 5 |

3. The following items are about activities you might do during a typical day. **Does your health now limit** you in these activities? If so, how much?

	(Circle One Number on Each Line)		
	Yes, Limited <u>a Lot</u>	Yes, Limited <u>a Little</u>	No, Not Limited <u>at All</u>
a. <b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. <b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying shopping bags.	1	2	3
d. Climbing <b>several</b> flights of stairs .	1	2	3
e. Climbing <b>one</b> flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking <b>more than a mile</b>	1	2	3
h. Walking <b>half a mile</b>	1	2	3
i. Walking <b>100 yards</b>	1	2	3
j. Bathing or dressing yourself	1	2	3



4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	<u>Yes</u>	<u>No</u>
a. Cut down the <b>amount of time</b> you spent on work or other activities?	1	2
b. <b>Accomplished less</b> than you would have liked?	1	2
c. Were limited in the <b>kind</b> of work or other activities?	1	2
d. Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)?	1	2

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	<u>Yes</u>	<u>No</u>
a. Cut down the <b>amount of time</b> you spent on work or other activities?	1	2
b. <b>Accomplished less</b> than you would have liked?	1	2
c. Didn't do work or other activities <b>as carefully as usual</b> ?	1	2

6. During the **past 4 weeks**, to what **extent** have your **physical health or emotional problems** interfered with your normal social activities with family, friends, neighbours, or clubs?

(Circle One Number)

Not at all .....	1
Slightly.....	2
Moderately.....	3
Quite a bit .....	4
Extremely.....	5

7. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None.....	1
Very mild.....	2
Mild.....	3
Moderate.....	4
Severe .....	5
Very severe.....	6

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all .....	1
A little bit.....	2
Moderately.....	3
Quite a bit .....	4
Extremely.....	5

9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

(Circle One Number on Each Line)

	<u>All of the Time</u>	<u>Most of the Time</u>	<u>A Good Bit of the Time</u>	<u>Some of the Time</u>	<u>A Little of the Time</u>	<u>None of the Time</u>
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and unhappy?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6
j. How much of your time has your health or emotional problems limited your social activities	1	2	3	4	5	6

10. Please choose the answer that best describes how **TRUE** or **FALSE** each of the following statements is for you.

**(Circle One Number on Each Line)**

	Definitely <u>True</u>	Mostly <u>True</u>	Don't <u>Know</u>	Mostly <u>False</u>	Definitely <u>False</u>
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

The following scale consists of a number of words that describe different feelings and emotions. Read each item and then circle the appropriate number to indicate to what extent you have felt this way **during the past week.**

		Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
1	Interested	1	2	3	4	5
2	Distressed	1	2	3	4	5
3	Excited	1	2	3	4	5
4	Upset	1	2	3	4	5
5	Strong	1	2	3	4	5
6	Guilty	1	2	3	4	5
7	Scared	1	2	3	4	5
8	Hostile	1	2	3	4	5
9	Enthusiastic	1	2	3	4	5
10	Proud	1	2	3	4	5
11	Irritable	1	2	3	4	5
12	Alert	1	2	3	4	5
13	Ashamed	1	2	3	4	5
14	Inspired	1	2	3	4	5
15	Nervous	1	2	3	4	5
16	Determined	1	2	3	4	5
17	Attentive	1	2	3	4	5
18	Jittery	1	2	3	4	5
19	Active	1	2	3	4	5
20	Afraid	1	2	3	4	5

**The following questions are designed to help us know how you have been feeling in the past week. Please answer each question by circling the appropriate number.**

**1. I feel tense or 'wound up':**

Most of the time	1
A lot of the time	2
From time to time, occasionally	3
Not at all	4

**2. I still enjoy the things I used to enjoy:**

Definitely as much	1
Not quite so much	2
Only a little	3
Hardly at all	4

**3. I get a sort of frightened feeling as if something awful is about to happen:**

Very definitely and quite badly	1
Yes, but not too badly	2
A little, but it doesn't worry me	3
Not at all	4

**4. I can laugh and see the funny side of things:**

As much as I always could	1
Not quite so much now	2
Definitely not so much now	3
Not at all	4

**5. Worrying thoughts go through my mind:**

A great deal of the time	1
A lot of the time	2
From time to time but not too often	3
Only occasionally	4

**6. I feel cheerful:**

Not at all	1
Not often	2
Sometimes	3
Most of the time	4

**7. I can sit at ease and feel relaxed:**

Definitely	1
Usually	2
Not often	3
Not at all	4

**8. I feel as if I am slowed down:**

Nearly all the time	1
Very often	2
Sometimes	3
Not at all	4

**9. I get a sort of frightened feeling like 'butterflies' in the stomach:**

Not at all	1
Occasionally	2
Quite often	3
Very often	4

**10. I have lost interest in my appearance:**

Definitely	1
I don't take as much care as I should	2
I may not take quite as much care	3
I take just as much care as ever	4

**11. I feel restless as if I have to be on the move:**

Very much indeed	1
Quite a lot	2
Not very much	3
Not at all	4

**12. I look forward with enjoyment to things:**

As much as ever I did	1
Rather less than I used to	2
Definitely less than I used to	3
Hardly at all	4

**13. I get sudden feelings of panic:**

Very often indeed	1
Quite often	2
Not very often	3
Not at all	4

**14. I can enjoy a good book or radio or TV programme:**

Often	1
Sometimes	2
Not often	3
Very seldom	4



We would like to know your views about the medicines prescribed for you:						
		Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
BS1	My health, at present, depends on my medicines	1	2	3	4	5
BS2	Having to take medicines worries me	1	2	3	4	5
BS3	My life would be impossible without my medicines	1	2	3	4	5
BS4	Without my medicines I would be very ill	1	2	3	4	5
BS5	I sometimes worry about long-term effects of my medicines	1	2	3	4	5
BS6	My medicines are a mystery for me	1	2	3	4	5
BS7	My health in the future will depend on my medicines	1	2	3	4	5
BS8	My medicines disrupt my life	1	2	3	4	5
BS9	I sometimes worry about becoming too dependent on my medicines	1	2	3	4	5
BS10	My medicines protect me from becoming worse	1	2	3	4	5

Please indicate how frequently you now experience the following symptoms as part of your heart failure by ticking the appropriate box.

	All of the time	Frequently	Occasionally	Never
1. Fatigue/lack of energy				
2. Nausea				
3. Breathlessness				
4. Chest pain				
5. Tightness in the chest/ arm/neck				
6. Upset stomach				
7. Sore eyes				
8. Sleep difficulties				
9. Dizziness				
10. Difficulty concentrating				
11. Irritability				
12. Stiff or sore joints				
13. Headaches				
14. Loss of strength				
15. Dry mouth				
16. Dry cough				
17. Swollen ankles				
18. Weight gain				
19. Weight loss				
20. Other _____				
21. Other _____				

We are interested in your own personal views of how you now see your heart condition. Please indicate how much you agree or disagree with the following statements about your illness by ticking the appropriate box.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
1. My heart failure will last a short time					
2. My heart failure is likely to be permanent rather than temporary					
3. My heart failure will last for a long time					
4. My heart failure is a serious condition					
5. My heart failure has had major consequences on my life					
6. My heart failure has become easier to live with					
7. My heart failure has not had much effect on my life					
8. My heart failure has strongly affected the way others see me					
9. My heart failure has serious economic and financial consequences					

	Strongly Agree	Agree	Neither agree nor disagree	Disagre e	Strongly Disagree
10. My heart failure has strongly affected the way I see myself as a person					
11. My heart failure will improve in time					
12. There is a lot which I can do to control my symptoms					
13. There is very little that can be done to improve my heart failure					
14. My treatment will be effective in curing my heart failure					
15. Recovery from my heart failure is largely dependent on chance or fate					
16. What I do can determine whether my heart failure gets better or worse					

The following items are about family and friends. Please indicate the extent to which you agree or disagree with each statement by circling the appropriate number.

		Very Strongly Disagree	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Very Strongly Agree
1	There is a special person who is around when I am in need	1	2	3	4	5	6	7
2	There is a special person with whom I can share my joys and sorrows	1	2	3	4	5	6	7
3	My family really tries to help me	1	2	3	4	5	6	7
4	I get the emotional help and support I need from my family	1	2	3	4	5	6	7
5	I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
6	My friends really try to help me	1	2	3	4	5	6	7
7	I can count on my friends when things go wrong	1	2	3	4	5	6	7
8	I can talk about my problems with my family	1	2	3	4	5	6	7
9	I have friends with whom I can share my joys and sorrows	1	2	3	4	5	6	7
10	There is a special person in my life who cares about my feelings	1	2	3	4	5	6	7
11	My family is willing to help me make decisions	1	2	3	4	5	6	7
12	I can talk about my problems with my friends	1	2	3	4	5	6	7

Having an illness often means doing different tasks and activities to manage your condition. How confident are you that you can:

		Not at all Confident	Somewhat Confident	Moderately Confident	Very Confident	Totally Confident
1	Do all the things necessary to manage your condition on a regular basis?	1	2	3	4	5
2	Monitor yourself for signs of change in your illness?	1	2	3	4	5
3	Judge when the changes in your illness mean you should contact your doctor/ nurse?	1	2	3	4	5
4	Take all your medications as prescribed?	1	2	3	4	5
5	Exercise regularly?	1	2	3	4	5
6	Follow a low salt diet?	1	2	3	4	5
7	Stick to the recommended daily fluid intake?	1	2	3	4	5

These questions concern how your heart failure has prevented you from living as you wanted during the last month. The items below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (No) and go on to the next item. If an item does apply to you, then circle the number rating how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

	Did your heart failure prevent you from living as you wanted during the last month by:	No	Very little				Very much
1	Causing swelling in your ankles, legs etc?	0	1	2	3	4	5
2	Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3	Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4	Making your working around the house or garden difficult?	0	1	2	3	4	5
5	Making your going places away from home difficult?	0	1	2	3	4	5
6	Making your sleeping well at night difficult?	0	1	2	3	4	5

	Did your heart failure prevent you from living as you wanted during the last month by:	No	Very little				Very much
7	Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8	Making your working to earn a living difficult?	0	1	2	3	4	5
9	Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10	Making your sexual activities difficult?	0	1	2	3	4	5
11	Making you eat less of the foods you like?	0	1	2	3	4	5
12	Making you short of breath?	0	1	2	3	4	5
13	Making you tired, fatigued, or low on energy?	0	1	2	3	4	5



	Did your heart failure prevent you from living as you wanted during the last month by:	No	Very little				Very much
14	Making you stay in hospital?	0	1	2	3	4	5
15	Costing you money for medical care?	0	1	2	3	4	5
16	Giving you side effects from medications?	0	1	2	3	4	5
17	Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18	Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19	Making you worry?	0	1	2	3	4	5
20	Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21	Making you feel depressed?	0	1	2	3	4	5

We are interested in how much each of the following statements applies to you. Please respond by circling the appropriate number.

		Not at all true	Barely true	Moderately true	Exactly true
1	I can always manage to solve difficult problems if I try hard enough	1	2	3	4
2	If someone opposes me, I can find means and ways to get what I want	1	2	3	4
3	It is easy for me to stick to my aims and accomplish my goals	1	2	3	4
4	I am confident that I could deal efficiently with unexpected events	1	2	3	4
5	Thanks to my resourcefulness, I know how to handle unforeseen situations	1	2	3	4
6	I can solve most problems if I invest the necessary effort	1	2	3	4
7	I can remain calm when facing difficulties because I can rely on my coping abilities	1	2	3	4
8	When I am confronted with a problem, I can usually find several solutions	1	2	3	4
9	If I am in a bind, I can usually think of something to do	1	2	3	4
10	No matter what comes my way, I'm usually able to handle it	1	2	3	4

**During the past week** (even if it was **not** a typical week), how much **total** time (for the **entire week**) did you spend on each of the following? (Please circle **one** number for each question).

		None	Less than 30 minutes per week	30 – 60 minutes per week	1 –3 hours per week	More than 3 hours per week
1	Stretching or strengthening exercises (range of motion, using weights, etc.)	0	1	2	3	4
2	Walk for exercise	0	1	2	3	4
3	Swimming or aquatic exercise	0	1	2	3	4
4	Bicycling (including stationary exercise bike)	0	1	2	3	4
5	Other aerobic exercise equipment (treadmill, rowing machine)	0	1	2	3	4
6	Other aerobic exercise – specify _____	0	1	2	3	4

The questions below ask about your self-care activities **during the last 7 days**. Please answer each question by circling the number that applies to you.

1. On how many of the last SEVEN DAYS did you eat a low salt diet?

0      1      2      3      4      5      6      7

2. On how many of the last SEVEN DAYS did you add salt to your food at the table?

0      1      2      3      4      5      6      7

3. On how many of the last SEVEN DAYS did you eat food to which salt had been added during cooking?

0      1      2      3      4      5      6      7

4. On how many of the last 7 days did you take your medicines as prescribed?

0      1      2      3      4      5      6      7

5. On how many of the last 7 days did you stick to the recommended daily fluid intake?

0      1      2      3      4      5      6      7

6. On how many of the last 7 days did you weigh yourself?

0      1      2      3      4      5      6      7

7. On how many of the last 7 days did you check your ankles for signs of swelling?

0      1      2      3      4      5      6      7

8. On how many of the last 7 days did you follow exercise recommendations?

0      1      2      3      4      5      6      7

Please help us improve our programme by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. *Please answer all of the questions.* We also welcome your comments and suggestions. Thank you very much, we really appreciate your help.

1. How would you rate the quality of the service you have received?

4  
Excellent

3  
Good

2  
Fair

1  
Poor

2. Did you get the kind of service you wanted?

1  
No, definitely not

2  
No, not really

3  
Yes, generally

4  
Yes, definitely

3. To what extent has our treatment met your needs?

4  
Almost all of my  
needs have been  
met

3  
Most of my  
needs have been  
met

2  
Only a few of  
my needs have  
been met

1  
None of my  
needs have  
been met

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes, definitely

5. How satisfied are you with the amount of help you have received?

1	2	3	4
Quite dissatisfied	Indifferent or mildly dissatisfied	Mostly satisfied	Very satisfied

6. Have the services you received helped you to deal more effectively with your problems?

4	3	2	1
Yes, they helped a great deal	Yes, they helped somewhat	No, they really didn't help	No, they seemed to make things worse

7. In an overall, general sense, how satisfied are you with the service you have received?

4	3	2	1
Very satisfied	Mostly satisfied	Indifferent or Mildly dissatisfied	Quite dissatisfied

8. If you were to seek help again, would you come back to our program?

1  
No, definitely not

2  
No, I don't think so

3  
Yes, I think so

4  
Yes, definitely

	Not at all					Very much
How helpful did you find the nurse intervention?	1	2	3	4	5	
To what extent do you think you were able to put into practice the information and advice provided?	1	2	3	4	5	
How helpful did you find the medication charts?	1	2	3	4	5	
How helpful did you find the weight charts?	1	2	3	4	5	
How helpful did you find the information booklet?	1	2	3	4	5	

Are you still using the medication charts?

Y / N

If no, for how long did you use them? \_\_\_\_\_

Are you still using the weight charts?

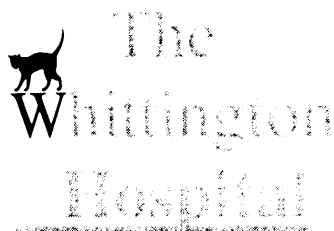
Y / N

If no, for how long did you use them? \_\_\_\_\_

Have you referred to the information booklet since leaving hospital? Y / N



## **APPENDIX F. PATIENT INFORMATION AND CONSENT FORMS**



## ***PATIENT INFORMATION SHEET***

Title of study: The evaluation of a self-management programme for patients admitted to hospital with heart failure

**Investigators: Dr. Suzanna Hardman, Professor Stanton Newman, Dr. Alex Zaphiriou, Kathleen Mulligan, Patsy Hargrave, Dr. Deblina Dasgupta, Dr Sandeep Gandhi**

We would like to invite you to take part in a research study. This information sheet will explain why and how the study is being carried out.

### **Purpose of the Study**

At the Whittington Hospital we are striving to improve the treatment we give to all our heart failure patients. As part of this improved service you will have already been seen by a cardiologist and you will have a further appointment with a cardiologist about 6 – 8 weeks after you have been discharged from hospital and again at 12 months.

The purpose of this study is to assess whether added input from a cardiac nurse specialist can provide additional benefits. In order to see whether the nurse specialist does provide additional benefit it is necessary to compare two groups of patients one of which is seen by the nurse and the other group who is not.

If this nurse-led intervention is shown to be beneficial, it should be made available to all patients. We also want to gain a better understanding of how patients and their partners understand their illness. This information will also assist us in providing better care.

### What will happen?

If you decide to take part in the study, you will be randomly allocated to one of two groups. One of the groups will have two meetings with a nurse during their hospital stay plus a home visit following discharge.

You will also be asked to complete some questionnaires before you go home and again when attending your out-patient appointments. The questionnaires will ask about how you are feeling and how you manage your illness. These assessments will take approximately 45 minutes to complete.

We need your permission to access the parts of your hospital records that relate to the study. We would also like your permission to access information held by the NHS and records maintained by the General Register Office so that we can follow up your health status and contact your new GP if you move out of the area.

During your stay in hospital and when you come back to outpatients, we normally monitor your kidney function as part of your care using blood tests. If you agree to help us with this research study we would like to take a small additional sample of blood on these occasions to give us an additional measure of how well your heart is pumping.

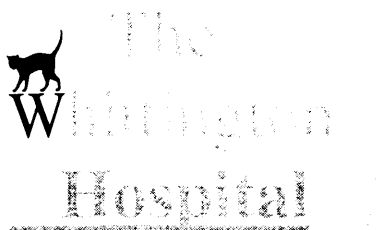
### **Confidentiality of records**

All information you give will be confidential; only the researcher will know that the information is related to you. The results of the study may be published in the medical literature, however your name and details will not be revealed.

**Please note. You do not have to take part in this study if you do not want to. If you decide to take part you may withdraw at any time without having to give a reason. Your decision whether to take part or not will not affect your care and management in any way.**

All proposals for research using human subjects are reviewed by an ethics committee before they can proceed. This proposal was reviewed by the Whittington Hospital Ethics Committee.

If you have any questions or would like any further information, please contact:  
Kathleen Mulligan Tel:



## **AGREEMENT TO PARTICIPATE IN RESEARCH PROJECT**

The evaluation of a Self-Management Programme for Patients admitted to Hospital with Heart Failure.

Investigators: Dr. Suzanna Hardman , Professor Stanton Newman, Dr. Alex Zaphiriou, Kathleen Mulligan, Patsy Hargrave, Dr. Deblina Dasgupta, Dr. Sandeep Ghandi.

1. Have you read the information sheet about this study? YES/NO
2. Have you had the opportunity to ask questions and discuss the study? YES/NO
3. Have you received satisfactory answers to all your questions? YES/NO
4. Have you received enough information about this study? YES/NO
5. Which doctor have you spoken to about this study? .....
6. Do you understand that you are free to withdraw from this study  
    \* at any time  
    \* without giving a reason for withdrawing YES/NO
7. Do you agree to take part in this study? YES/NO
8. Are you happy for us to approach your spouse/partner/carer to take part in the study? YES/NO
9. Do you give permission for information held by the NHS and records maintained by the General Register Office to be used to keep in touch with you and follow up your health status? YES/NO

Signed.....Date.....

Name in Block Letters.....

Doctor.....